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The Use of Extended Wear Contact Lenses in the Aviation Environment: An Armywide Study

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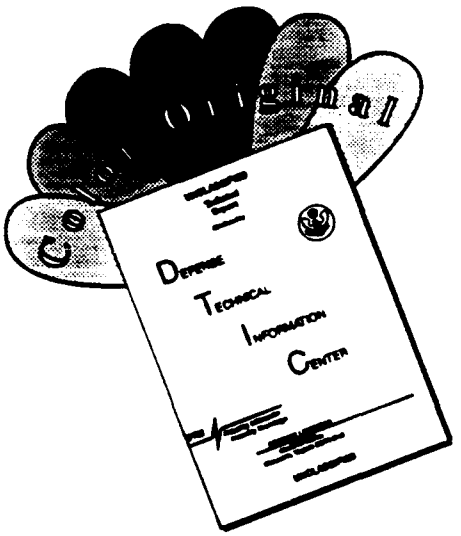

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Standard refractive error correction options for the M-43 protective mask have proven to be incompatible with the Helmet Display Unit (HDU) component of the AH-64 "Apache" Integrated Helmet and Display Sighting System (IHADSS). Glue-on and outsert packages push the HDU, a Maxwellian-view virtual imaging system, far enough from the spectacle-wearing aviator's eye to significantly reduce the available field-of-view. Consequently, portions of critical peripheral instrumentation and weapon system overlays cannot be visualized. In November 1988, the U.S. Army Aeromedical Research Laboratory (USAARL) initiated the AH-64 contact lens research protocol to provide both an interim readiness fix and to develop a comprehensive database on contact lens wear in a variety of environments.
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The protocol was organized from three perspectives with concerns directed toward operational and flight safety, ocular health, and corneal physiology issues, and concluded at the end of September 1991. Fundamental operational and safety data were chronicled, along with written questionnaires, to assess subjective effectiveness of routine contact lens use. Ocular health complications were collated from the aviation medicine, optometric, and ophthalmological communities. Clinical and physiological data were gathered by one USAARL optometrist, and two contract civilian optometrists and their supporting technicians.

In September 1990, a general aviation version of the M-43 protective mask was identified for early fielding without its spectacle outsert. All spectacle-wearing aircrew (pilots, crewchiefs, door gunners, flight medics, and flight surgeons) deploying to Southwest Asia were examined for possible contact lens wear under the auspices of the existing Armywide contact lens research protocol. Ten Army optometrists and 10 technicians performed the additional examinations at over a dozen U.S. locations and 3 locations in Europe. Four of the optometrists permanently deployed to Saudi Arabia in direct support, and for the duration, of Operations Desert Shield/Storm. The original protocol included 238 subjects, while the Desert Storm portion (general aviation) added 344 subjects. Roughly 450 of the total 582 contact lens-wearing subjects served in Southwest Asia on Operation Desert Storm. Overall initial fitting success was 72 percent (624 fitted out of 868 volunteers). Unsuccessful fitting attempts fell into four general groupings: presbyopes, high astigmats, extremely steep or flat corneal curvatures, and preexisting medical conditions. Wearing success was 67 percent; 42 subjects withdrew or were discontinued from lens wear over the course of the study. The primary dissatisfiers related to the same groupings affecting fitting success.

The original protocol used a three-tier contact lens fitting system, with the initial lens of choice being a moderate to high water content disposable extended wear soft lens. Backup lenses consisted of a low water content standard extended wear soft lens utilized on a disposable basis, and a rigid gas permeable (RGP) lens used with a chemical disinfection system. Both types of soft lenses had analogous diameters and base curves (14.0 mm and 8.8 mm, respectively). The RGP lenses were not fielded on Operation Desert Storm because of concerns for possible foreign body intrusion from blowing dust and dirt. Limited RGP use by Desert Storm participants from the original protocol confirmed this concern. The original protocol wearing schedule was set at a maximum of 7 days/6 nights of extended lens wear. Desert Storm

19. ABSTRACT (Continued)

subjects were advised to follow a more conservative 3-day/2-night schedule. The subjects were instructed that the night of lens removal was to be passed without any new lens wear; worn soft lenses were to be discarded, and RGP lenses cleaned, disinfected, and stored overnight. After at least one full night of lens-free sleep, the subjects were instructed that they could apply a new soft lens, or resume wear of the cleaned and disinfected RGP lenses.

Over the 33 months of the study, there were minimal changes noted in clinical appraisal of the tarsal conjunctiva, possible corneal edema, tear BUT, and tear production for all subjects. Mild changes were evident in evaluation of the bulbar conjunctiva, limbal injection, corneal vascularization, rose bengal staining, and fluorescein staining for the original protocol subjects. Mild to moderate changes were seen in many of the Desert Storm subjects. However, despite the harsh desert environment, contact lens wear in Southwest Asia, as assessed by slit lamp evaluation, was much less stressful than expected.

There have been six cases of bacterial ulcerative keratitis; two during the AH-64 portion of the protocol, one associated with deployment on Operation Desert Shield, none documented during the Desert Storm combat phase of the deployment, and three occurring during or shortly after redeployment *from* Southwest Asia. While affected aircrew were temporarily grounded from flight duty during the course of the infection, all returned to full flight duties after resolution of the acute infection. Visual acuity recovered to 20/20 or better in all six subjects. The resultant calculated risk for ulcerative keratitis was 1 per 112 subjects per year of contact lens wear (8.9/1000/year). Civilian estimates have placed the risk of infective ulcerative keratitis from 2.1/1000/year to 15/1000/year to 48/1000/year. Although this study had a relatively low number of subjects compared to many civilian studies, the occurrence of this severe infection fell within the range established in the published literature.

The subjective evaluation of routine contact lens wear was high in garrison, field, and combat conditions, as were performance assessments. Combat missions included: attack, troop transport, equipment transport, surveillance, intelligence, special operations, and medical evacuation. The Apache radar interdiction mission into Iraq on 16 January 1991, which initiated Operation Desert Storm, consisted of several contact lens wearers, including the mission commander. By questionnaire, subjects overwhelmingly approved contact lens use in all settings; 95 percent expressed greater combat readiness and effectiveness with contact lenses; 98 percent felt contact lens

19. ABSTRACT (Continued)

use (and maintenance) in the cockpit had no adverse impact on safety of flight; and 98 percent endorsed the routine use of contact lenses in the performance of flight duties.

Based on the clinical, ocular health and subjective questionnaire data, contact lens wear by Army aircrew is a viable alternative to spectacle wear. However, because of unique difficulties encountered in attempting to fit presbyopes, high astigmats, and those with extreme corneal curvatures (either very flat or very steep), one-third of spectacle-wearing aircrew may not be able to successfully wear contact lenses. This fraction likely will decrease in a routine clinical program if lens parameter availability is expanded beyond those used in this study. Nevertheless, routine contact lens wear will represent only a partial solution to Army aviation's spectacle incompatibility problem. Therefore, developmental hardware alternatives must be included in future system programming or many air crewmembers will be prevented from performing certain flight duties.

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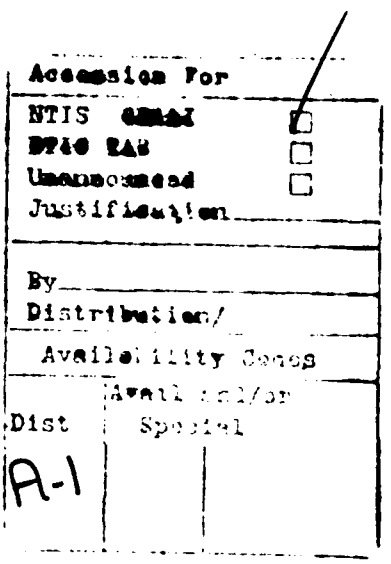

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Introduction

Purpose

The purpose of this study was to determine the compatibility of extended wear contact lenses for the U.S. Army aviation environment on a worldwide basis. The specific project objectives were to:

1. Determine success rates in the fitting and the wearing of contact lenses in a volunteer sample of ametropic aircrewmembers on a worldwide basis.

2. Document the descriptive characteristics of the volunteer sample of Army aviation and make projections concerning the Army aviation population as a whole.

3. Characterize the physiological/biochemical response of the cornea to contact lens wear, and quantify potentially altered contact lens characteristics after application onto the eye.

4. Document incidence of corneal complications and attempt to identify underlying mechanisms of pathology.

5. Obtain a quantifiable assessment of contact lens acceptability and identify the operational impact of contact lens wear associated with the occupational tasks and conditions unique to Army aviation.

Approach

Volunteer ametropic aircrewmembers were fitted with extended wear contact lenses. It should be stressed that this was a contact lens research program, not a field test of contact lens use; as such, only volunteer participants were used. The voluntary nature of this program was repeatedly stressed to participants so that they fully understood their right to not participate or to withdraw at any time. Periodic clinical monitoring was accomplished to safeguard the ocular health of the subjects and their continued safety of flight. Combined with the clinical monitoring process were a number of tests designed to assess the physiological and biochemical response of the cornea to contact lens wear. Operational effectiveness was assessed by way of volunteer subjective responses concerning positive and negative effects of CL wear as reported to their unit flight surgeon, and as reported on a quarterly questionnaire.

It should be noted that Army Regulations (AR) 40-5, AR 40-8, AR 40-63, and AR 40-501 express certain prohibitions associated with the use of contact lenses by Army aircrewmembers. A waiver of policy relating to the use of contact lenses was approved by The Office of The Surgeon General for the wear of contact lenses under controlled investigational conditions, and more recently, in conjunction with Operation(s) Desert Shield and Storm. An individual waiver for each subject participating in the study was initiated by the subject's unit flight surgeon via an abbreviated aeromedical summary, which stipulated that only one contact lens wearer be allowed on any one individual flight. The waivers were processed through the Aeromedical Center at Fort Rucker, and then through the Total Army Personnel Command (PERSCOM) for final waiver approval.

Military significance

The role of vision in aviation has always been an important one. Now, with the ever-increasing technological complexity of the man-machine interface, optimal visual performance has become absolutely essential to aircraft operation. However, sophisticated electro-optical display devices often can present a compatibility problem with spectacles; the use of specialized environmental protective systems can further confound this problem. As a result, spectacle wearing aviators, many with advanced aviation skills, could be deselected from duty in certain aircraft. The use of extended wear contact lenses could help maintain the pool of qualified aviators available for deployment in these sophisticated aviation systems.

Background

Statement of the specific problem

Traditionally, prospective aviators have had to meet stringent vision standards for acceptance into a training program. Over the years some standards have been subject to waiver, the requirement for relative emmetropia being one of them. This, in conjunction with the reduction of other standards, and with the development of late-onset, maturational myopia in some individuals, has led to the development of a sizeable ametropic population in the Army aviation community. Currently, approximately 23 percent of all Army aviators wear a spectacle correction (Schrimsher and Lattimore, 1991).

Specific problems have emerged involving the integration of spectacle wear with certain avionics systems. The standard issue aviator spectacle is not compatible with the Integrated Helmet Display and Sighting System (IHADSS) of the Advanced Attack Helicopter, AH-64. As a result, a modified right eye-piece was developed for the aviator spectacle frame. This modification,

however, still does not prevent IHADSS combiner lens positioning from being a difficult process. Unauthorized individual modifications, designed to move the right spectacle lens closer to the face, have forced some individuals to trim their eyelashes so that they won't rub against the repositioned lens. Yet, even this extreme measure fails to solve the positioning problem.

The optical relay tube (ORT), found in both the AH-1 and AH-64, presents another spectacle compatibility problem. These instrumentation interfacing difficulties have a detrimental effect on operational efficiency. The reduction or elimination of these difficulties are essential to effective combat flight operations.

The M-43 protective mask for AH-64 aviators, and the general aviation version of that mask, present yet another problem. Initially, it was anticipated that ametropic aviators would have their correction incorporated onto the protective mask eyepiece. This system adaptation has been shown to induce a number of visual problems which lead to an incompatibility with the Integrated Helmet and Display Sighting Subsystem (IHADSS) or Helmet Display Unit (HDU) on the Apache. As a result, ametropic aviators are unable to optimally operate the AH-64 in a chemically contaminated environment with the glue-on correction. In addition, there has been a recent question concerning night vision goggle (NVG) compatibility with the optical outsert designed for the new general aviation version of the M-43 mask.

The use of contact lenses by ametropic aircrewmembers offers a potential solution to these problems. However, because Army aviation's combat mission requires an immediate response, the only feasible type of contact lens would be extended wear in nature. The Army aviator's immediate combat responsiveness requirement would not permit adequate time for lens preparation and insertion prior to the mission. Furthermore, disposable lenses are desirable in order to minimize cleaning and disinfection problems, particularly those associated with an operational field setting. It should be stressed that while disposable lenses may help minimize the potential for ocular infection, other problems can be induced by the use of contact lenses on an extended wear basis. It is the ultimate objective of this study to document both the benefits and deficiencies of contact lens wear so that the Army can determine the overall acceptability of this visual correction option.

Literature review introduction

Recent technological advances have had a major impact on military aviation. While modern methods of providing visual information via electro-optics/visionics systems have extended

the aviator's operational envelope, these devices are becoming increasingly incompatible with spectacle wear. Due to unique stringent regulations, the Navy and Marine Corps do not allow service members with high refractive errors (i.e., uncorrected visual acuity worse than 20/70) to pilot aircraft equipped with these advanced visionics systems; if an aviator develops an excessive refractive error, administrative reassignment as a flight officer (bombardier/navigator, radar intercept officer) ensues (Markovits, 1988). Alternatively, Navy/Marine Corps aviators with uncorrected visual acuity from 20/25 to 20/70, correctable to 20/20 or better, are permitted to operate these high performance aircraft. This type of partial deselection process has, for the moment, been rejected by the Army and Air Force. Since close to 23 percent of Army aviators (Schrimsher and Lattimore, 1991) and 27 percent of Air Force aviators (Dennis, 1988) are ametropic (spectacle wearing), and since an increasing percentage of training applicants are ametropic, alternative means of providing a refractive error correction need to be investigated.

One alternative being considered is the utilization of a contact lens correction. Current and past armed forces regulations have prohibited the wearing of contact lenses by aviators while flying. However, waivers to these regulations have been approved at certain locations where controlled scientific investigations are being conducted. Because of differences in missions and operational scenarios, research efforts are being directed along somewhat divergent paths. Air Force concerns concentrate on low atmospheric pressure/low ambient oxygen issues, low relative humidity, and high g-force effects on daily lens wear. Army concerns center on the operational field environment, its impact on proper lens hygiene (cleaning and disinfection), and the physiological/biochemical response of the cornea to extended contact lens wear. Since the question of contact lens use by aviation personnel is a matter of current interest throughout the aviation and aeromedical communities, this review provides a general overview of salient issues and considerations.

Aviation literature review

A number of types of contact lenses have been evaluated within the aviation environment. The first Army aviation study was in 1974 (Crosley, Braun, and Bailey). Of concern at the time was the fact that "hard" polymethylmethacrylate (PMMA) contact lenses were prone to dust particle interference between the cornea and the contact lens when worn by ground troops in an operational environment (Rengstorff, 1965, and 1972; LaPiana, 1980). Since Army aviators routinely were exposed to dusty environments, the PMMA lenses had been ruled out as an Army aviator optical correction. The Bausch and Lomb (B&L) "Soflens"

was found to be independent of dust-induced foreign body problems. However, an unacceptable variability in visual acuity did result. A parallel study (Polishuk and Raz, 1975) obtained similar results concerning both absence of dust and dirt problems and variable visual acuity in a population of Israeli military and civilian pilots. Acuity variation was not attributed to any specific origin.

Since soft contact lenses have a moderate to high water content, other studies have been concerned with the effects of both low atmospheric pressure and low relative humidity on lens dehydration and corneal health. A number of clinical case reports concerning extended passenger travel difficulties with contact lenses surfaced in the literature (Jagerman, 1973; Casebeer, 1973; Corboy and Tannehill, 1973) serving to stimulate specific laboratory investigations. A hypobaric chamber study, simulating altitudes up to 30,000 feet on the B&L "Soflens," failed to demonstrate an effect on contact lens wearability (Eng, Rasco, and Marano, 1978). However, in a study by Forgie (1981) with simulations at 25,000 feet for 2.5 hours and at 9,000 feet for 6 hours, subjects demonstrated some tear film debris and experienced minor discomfort. Despite these findings, aircraft control was not significantly degraded, and visual acuities were said not to be affected. Forgie's findings were in agreement with those of Hapnes (1980), whereby subjects were kept at 1/2 atmosphere for 4 hours. All subjects exhibited minor objective corneal changes that appeared to be epithelial in origin. More recently, the U.S. Air Force conducted a series of hypobaric chamber "flights" in order to assess soft contact lens wear at altitude (Flynn et al., 1988). Indicators of physiological stress to the cornea (by slit lamp examination) showed heightened responses at altitude with contact lenses. However, these changes occurred without measurable degradation in vision and did not preclude the normal wear of soft contact lenses.

Another recent study (Flynn et al., 1987) has documented subcontact lens bubble formation in a hypobaric chamber protocol. Soft contact lens bubble formation was limited to the lens periphery, and was without sequelae to vision or corneal epithelium integrity. Rigid, gas permeable lens bubble formation was primarily central in location, with potentially adverse effects on vision and the corneal epithelium. It should be noted that similar bubble formation has been documented in hyperbaric decompression studies for the Navy (Simon and Bradley, 1980; Molinari and Socks, 1987).

Since PMMA lenses had a propensity for accidental displacement from the central cornea, centrifuge studies also have been performed on soft contact lens-wearing subjects (Forgie, 1981). A +5.1 G_z force at eye level induced a subject-variable displacement, but never enough to leave the pupil

uncovered by the optical zone of the lens. An anecdotal report concerning one fighter pilot (Nilsson and Rengstorff, 1979) stated the individual, over a 3-year period, encountered no problems with gravity forces up to +6 G_z. In U.S. Air Force centrifuge studies, forces of up to +8 G_z failed to significantly interfere with the visual acuity and physical fit of soft contact lens wearing subjects (Flynn et al., 1985). Similar work with rigid gas permeable lenses has been recently completed[1].

Draeger, in the Federal Republic of Germany (1981), addressed all three of the above areas of interest in one study. His results indicated: (1) low atmospheric pressure does not induce a problem in modern, well-fitted lenses; (2) low humidity does not cause significant corneal or conjunctival irritation; and (3) high g loads do not significantly affect lens positioning on the cornea. Braithwaite (1983) described the experiences of seven British Army aviators wearing several different types of contact lenses; among the conclusions was the statement that soft lenses were generally better tolerated than hard lenses. In another study from the United Kingdom, 17 officer aircrew were fitted with medium (50 percent) and high (75 percent) water content extended-wear soft contact lenses (Brennan and Girvin, 1985). The subjects were exposed to hypoxia, rapid decompression, pressure breathing, vibration, extremes in climate, g forces, and the prolonged wearing of an aircrew respirator during the course of the flight-simulation study. The authors reported that visual performance of soft contact lens-wearing subjects, under the flight simulation ground-testing conditions, did not differ significantly from the control group. It was concluded that soft contact lenses are acceptable for aircrew use. Reportedly, the Royal Air Force currently is authorizing contact lens use on a limited basis (Crosley and Bachman, 1985).

In contrast to the above conclusion, two retrospective, epidemiological studies have suggested that civilian contact lens-wearing aviators may be more likely to be involved in a mishap than the spectacle-wearing and visually "normal" civilian aviation populations (Dille and Booze, 1980 and 1982). Despite the apparent controversy, Air Force researchers have stated contact lenses appear to be a viable alternative for their own spectacle compatibility problems. However, they did express concerns regarding implementation of widespread usage (Tredici and Flynn, 1987).

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[1] Poster presentation by Dennis, R., and Miller, B. at the American Academy of Optometry Annual Meeting, December 1989, New Orleans.

The U.S. Air Force recently concluded a field test of contact lens use by Tactical Air Command (TAC) aviators (Dennis, 1988). The joint operational test was conducted by the U.S. Air Force School of Aerospace Medicine (USAFSAM) and the Tactical Air Warfare Center (TAWC). Eighty-five aircrewmembers from five TAC bases participated in this test of two different water content soft contact lenses. Although divided into three separate phases with interim completion dates, the conclusion of the study and the final report will be published soon. Based on preliminary results, the Air Force has approved the use of soft contact lenses for all ametropic aviators[2].

Several U.S. Army organizations have addressed a variety of aspects of contact lens wear in military aviation. In order to develop relative safety patterns in established Army rotary-wing systems, an initial feasibility study of contact lens wear involved volunteer National Guard aviators at Fort Indiantown Gap, Pennsylvania (Halliday, 1985). Plano powered, FDA approved extended-wear contact lenses were fitted to the nondominant eye of volunteer aviators. Of 35 volunteers, 34 were adequately fitted with a 55 percent water content soft lens. Administrative (scheduling) losses totalled 5, so that the actual subject sample size was 29. During the 63-day course of the 30-day lens wear protocol, six subjects were unsuccessful in the program (four as a result of mild conjunctivitis believed to be seasonal in nature, one as a result of a corneal abrasion and secondary withdrawal, one resulting from lost lenses with no access to replacement lenses). No incidents of operational significance were reported, and the author summarized that this monocular fitting methodology could be applied to large scale research efforts in the future.

Following that preliminary report, another investigation conducted by the U.S. Army Aeromedical Research Laboratory (USAARL) utilized Army ametropic aviators qualified in a number of different aircraft as volunteer contact lens wearers, in order to further document aviation safety and flight operations issues (Bachman, 1988). Forty-four aviators were fit with extended-wear contact lenses, both soft and rigid gas permeable; the lenses were worn on a 7-day/6-night schedule. That is, after the initial fitting, the lenses were worn continuously for 7 days and 6 nights. The lenses were then removed prior to retiring for the 7th night, and were reapplied the following morning after utilizing an appropriate disinfection and lens-care regimen. Postfitting followup examinations were provided on day 1, day 8,

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[2] USAF Contact Lens Implementation Plan (89-73) dated 21 June 1989.

and every 30 days thereafter. The study ran for 6 months with an 86 percent wearing success rate.

Prior to the initial contact lens fitting, the mean flying time for the subject sample was 2,136 hours; over the 6-month period of the study, the mean flying time for the contact lens wearing subjects was 294 hours. During the course of the study, there were no groundings for contact lens related reasons, and there were no aircraft accidents involving the test subjects. Subjective performance assessments rated the contact lenses utilized as being superior to spectacle wear for a vast majority of the aviators for: preflight (68 percent), takeoffs (83 percent), routine flight (83 percent), nap-of-the-earth (NOE) flight (89 percent), night vision goggle (NVG) flight (88 percent), instrument flight (83 percent), and mission oriented protective posture (MOPP 4; i.e., in full protective clothing with protective mask in place) conditions (100 percent).

Temporary discontinuance of contact lens wear occurred for six pilots a total of nine times. The affected aviators merely wore their spectacles in lieu of the contact lenses. A total of 6 of the original 44 subjects were unable to complete the study. Reasons for withdrawal from this voluntary study were: acuity (two) and discomfort (four). In summary, the initial feasibility study demonstrated the safe short-term use, both in medical and flight terms, of extended-wear contact lenses by Army aviators.

A number of reports have documented the use of contact lenses in a military field environment other than aviation. Gauvreau (1976) fitted soft lenses to freefall parachutists. If protective goggles remained on the eye throughout the course of the jump, no untoward effects of soft lens wear were encountered. However, if the protective goggles and/or the soft lenses were blown off the face, the postjump slit lamp evaluation revealed corneal epithelial punctate staining and temporarily reduced visual acuity. The staining was interpreted as an indicator of lens adherence to the superficial aspect of the corneal epithelium.

Van Norren (1984) submitted a questionnaire to 100 Dutch Army contact lens wearers immediately after a large-scale field exercise. Sixty percent of the contact lens wearers were able to wear their lenses throughout the duration of the exercise. Twenty percent of the respondents did not wear their lenses at all on the exercise, while 20 percent had started the exercise wearing their lenses, but were forced to discontinue wear for one reason or another. In effect, of those respondents attempting to wear their lenses during the course of the exercise, 75 percent were successfully able to do so (i.e., 60 of the 80 subjects attempting to wear their lenses during the field training exercise were successful).

Another Dutch Army study (Rouwen and Rosenbrand, 1986) evaluated soft contact lens wear by 28 soldiers over a 3-month period. During that time, 29 percent of the subjects were forced to discontinue lens wear, yielding a success rate of 71 percent. Similarly, a combined U.S. Army study (TCATA Test Report, 1986; Bachman et al., 1987) of 215 armor troops over a 6-month period established a success rate for contact lens wear in garrison and field training environments at 74 percent.

Related anatomy and physiology

Precorneal tearfilm

The primary refracting surface of the eye is the front surface of the precorneal tearfilm. The largest refractive index difference along the ocular light path, from the external environment to the retinal photoreceptors, is found at this media transition point from air to fluid. Therefore, the precorneal tearfilm plays a critical role in vision.

While the tearfilm is referred to as a single refracting surface it is actually a complex laminate of three layers. The anterior-most layer is composed of a thin film of oil or lipid produced by the meibomian glands lining the margins of the upper and lower eyelids or tarsus. This ultrathin film of oil is theoretically responsible for preventing abnormal evaporation of underlying fluids. However, it may also play a significant role in the stabilization of tearfilm thickness and refracting power by way of surface tension dynamics. While little information is available concerning excess lipid production, a deficiency in this layer can lead to difficulties in contact lens wear (this will be discussed later).

The second layer of the tearfilm is an aqueous or water media produced primarily by the lacrimal gland located at the superior temporal aspect of the anterior orbit, situated partially under the orbital rim. Additional components are contributed by the accessory lacrimal glands of Krause and Wolfring. The watery product is a complex dialysate containing a vast array of ionic solutes, proteins and protein fragments, and associative immunoreactive components. The total protein content of tears is about 0.5 percent. The water layer is the thickest, accounting for a major portion of the 7 micrometer (um) deep tearfilm. It is in this layer that tearfilm-contact lens-cornea interaction takes place. Total estimated tear volume is 7 microliters of which 1.1 microliters is within the precorneal tearfilm and the rest is within the marginal strips and the fornices (Mishima et al., 1966).

The last layer is mucoid in nature, directly abutting against the corneal epithelium. The mucous is secreted by goblet

cells located within the bulbar and palpebral conjunctiva. The uniquely structured mucous orients itself so that a highly polar portion of the molecule faces the water layer, while at the same time a nonpolar portion faces the cornea. Such a molecular orientation allows the irregular anterior surface of the corneal epithelium to be transformed into a smooth optical surface that also provides a uniformly charged field enhancing distribution of the overlying watery layer. In isolation, and in concert, each of the three tearfilm layers plays an important role in the establishment of a congruous refracting surface.

Cornea

The cornea is an optically transparent layer of tissue serving as an optical window for the passage of light into the eye. As such, the physical structure and shape of the cornea has considerable influence on the quality of vision. It is composed of five discrete strata: the epithelium, anterior limiting lamina (classically referred to as Bowman's layer), the stroma, the posterior limiting lamina (classically referred to as Descemet's layer), and the endothelium. Each can be influenced by contact lens wear.

The epithelium is the anterior-most layer and traditionally thought to be the most influenced by the presence of a contact lens. The epithelium can be 50 to 90 micrometers in thickness and consists of several sublaminae, each with characteristic cell groups: superficial or squamous cells, wing cells, and basal or columnar cells.

The deepest layer of the epithelium is the basal layer. The basal cells are tightly attached to their own basement membrane by hemidesmosomes, which in turn juxtaposes with Bowmen's layer or the anterior limiting lamina. These cells are the most metabolically active, serving as the source for all other epithelial cells by way of mitosis. The mitotic process serves to push older cells forward into the midepithelium.

These matured cells, within the intermediate areas of the epithelium are termed wing cells. The wing cell layer is roughly two cells thick; the cell shape is slightly vertically compressed compared to basal cells. Moderately active metabolically, wing cells are closely yoked by both adherent areas (zonula adherens) and by gap or ionic junctions.

The outermost layer is the squamous or superficial cell layer. Cells making up this layer are closely connected physically by zonula occludens, which serve as a barrier to passive fluid passage. Superficial cells are rough on the surface, possessing many microvilli. As the superficial cells migrate toward the corneal exterior these microvilli increase in

size; their presence allows for an enhanced spreading and smoothing of mucous, which translates to a stable tearfilm. Surface cells eventually are sloughed into the tearfilm. The epithelial cell lifespan from basal cell formation to desquamation is approximately 7 days.

The anterior limiting lamina is histologically distinct from the basement membrane of the epithelium. However, at the limbus, the lamina appears to merge with the basement membrane of the bulbar conjunctiva. This suggests a possible barrier role to enhance the function of the epithelial basal cell layer and its basement membrane. Totally acellular, this layer consists of small diameter (25 nm) collagen fibrils that are arranged randomly in all three dimensions. These physical characteristics clearly differentiate this lamina from the stroma.

The stroma makes up 90 percent of the total corneal thickness. Stromal collagen fibers are close to 50 nm in diameter and arranged in a periodic pattern. The stroma is subdivided into 250 laminae of fibers. Each lamina has its collagen fibers running in parallel from limbus to limbus. Yet the orientation of these laminae, compared to one another, is scattered randomly across the cornea. The result is a very strong layer capable of effectively resisting any stretch or shear forces. This regular placement of fibers permits optical clarity. If excessive fluid accumulation occurs, disrupting this periodicity, clarity can be lost. Within the collagen fiber matrix are cellular and ground substance components. Keratocytes are the cells responsible for the manufacture of both the collagen fibers and ground substance, thereby playing the overall engineering role in the construction and maintenance of the stroma. Other cellular components fall within the general category of defense cells, including lymphocytes, macrophages, monocytes, and neutrophils. Corneal sensory nerves also can be found within the stroma. The nerves enter the cornea at the limbus and proceed radially toward the apex. Anterior branching occurs across the cornea, with nerve penetration reaching forward to the level of the basal layer of the epithelium. Although superficial corneal sensitivity suggests nerve fiber presence close to or at the corneal surface, no such innervation has been shown anatomically.

The posterior limiting lamina, yet another layer of regularly arranged collagen fibrils, is produced by the underlying corneal endothelium. Continually increasing in thickness throughout life, this layer may also function as a basement membrane, since the endothelium has no classic, anatomical basement membrane. However, the posterior limiting lamina is not a good barrier to passive fluid and electrolyte movement and also has no solid attachment to the endothelium, both characteristics of a true basement membrane.

The endothelium is a single cell layer thick sheet of hexagonal shaped cells lining the posterior surface of the cornea, interfacing with the anterior chamber's aqueous humor. As previously mentioned, tight attachment to the posterior limiting lamina is lacking; local attachments to adjacent cells are maintained closely by way of adherens occludens complexes. At birth, the endothelial cells are very nearly alike in apparent size and shape. Increasing variations in cell size and shape occur with aging. Other factors have been known to stimulate these changes: ultraviolet radiation, contact lens wear, and toxic exposures. The apparent function of the endothelium is to maintain corneal clarity by keeping the stroma in a relatively dehydrated state. Membrane-localized enzymes are responsible for cellular pumping of fluid out of the cornea into the aqueous. Changes in endothelial morphology have been linked to deficits in cell pump function. Therefore, contact lens wear could have a functional effect on endothelial physiology.

Introduction to soft contact lenses

So called soft contact lenses are composed of polymers that have had hydrophilic subgroups incorporated into the polymeric chain. The resulting material is capable of absorbing water. Soft contact lenses can be manufactured by two different basic methods; lathe cutting and spin casting. The unhydrated polymer is cut into a generic "button," which then can be lathe cut or shaved to specific parameters. Once made to specification, the lens is hydrated by chemical means. Lathe cut lenses usually are superior in optics, but have a limited, circumscribed optical zone which can be distracting to the discriminating wearer on peripheral gaze or at night. The spin cast method involves the injection of forming hydrated polymer into molds spinning at adjustable rates. At higher rates of spin more plastic is displaced toward the periphery of the mold, thereby permitting a minus powered lens to be obtained. Computer regulated manufacturing has reduced the cost of spin cast lenses. The optical quality of spin cast lenses has been suspect at times, as well as the quality of the lens edge. However, a spin cast lens has an optical zone very nearly equal to that of its overall diameter and subjectively translates to a superior field-of-view by discriminating wearers. Actual testing has not yet been conducted to verify these partisan reports.

A successful contact lens fitting provides clear stable vision combined with physical comfort, without undue risk of secondary complications. Hydrogel lenses are so "soft" that they will conform to any distortion in the shape of a cornea so that moderate amounts of astigmatism are not correctable optically. Therefore, visual acuity in some cases may not be correctable to 20/20 or better with soft contact lenses. Excessive discomfort related to the mere physical presence of a soft lens is very

rare; any reports of discomfort should be closely investigated by slit lamp evaluation. Secondary complications can represent a wide range of conditions from a normal physiological variant to physical ocular degeneration. A detailed slit lamp examination can help differentiate the benign physiological entity from the pathological disease state.

The extent of soft contact lens availability has increased with the development of high water content lenses. The first hydrophilic material was 40 percent water, but to make it manageable for handling as a contact lens, cross-links were induced which cut the water content to 38.6 percent. The newer lenses have a copolymer added to the matrix; the copolymers have additional hydrophilic binding sites which attract water. Thus, the water content of the lens can be increased to as much as 78 percent, but it should be noted that further lens handling manageability is lost as a tradeoff. In an effort to improve ease of handling, the lens manufacturers often increase the lens thickness. This is important to remember, because water percentage of a lens material only indirectly reflects oxygen transmissibility (T). Factors directly affecting oxygen transmissibility are: oxygen diffusivity (D), oxygen solubility (K), and thickness (L) of the material. The mathematical representation is: $T = DK/L$. As a result of this mathematical relationship, a high water content material does not necessarily signify greater oxygen transmissibility, since high water content lenses generally are thicker than other lenses (Sarver et al., 1981).

In the case of moderate to high water content soft lenses (greater than or equal to 55 percent water) that are manufactured as disposable lenses, improved transmissibility can be achieved by using a thinner lens profile. Such a lens is very comfortable to wear, and since it is disposable, fragility in handling is not a pertinent issue. However, such disposable lenses recently have been tested on a 2-week daily wear basis with routine cleaning and disinfection. Initial trials led to many torn lenses. Reportedly, with practice, daily cleaning of such lenses can successfully be accomplished after an introductory learning curve is established.

Review of clinical issues

Superficial punctate keratitis

Some soft contact lens complications can occur that are directly related to lens wear and are observed often enough to be considered common in nature (Friend, 1983; Rao, 1984; Efron and Holden, 1986; Holden et al., 1986; McNally et al., 1987; Osborn and Zantos, 1988). These include breaks in epithelial integrity,

which can be identified through use of a water-soluble sodium-fluorescein stain. Certain patterns of corneal fluorescein staining can be diagnostic of nocturnal corneal exposure, preservative toxicity, subcontact lens foreign body presence, and hydrogel lens desiccation. These conditions will readily resolve within hours to days after removal of the offending contact lens. In addition, physical characteristics or parameters of the contact lens may be modified selectively to minimize/eliminate these states.

Neovascularization

Contact lens wear can stimulate blood vessel growth from the corneal limbus or perimeter into the cornea proper. While this phenomenon commonly is associated with extended soft lens wear, it also can be present in a daily lens wearer, as well (Weinberg, 1977; Rao, 1984). Since the cornea normally is avascular and optically clear, the corneal haze that accompanies this neovascularization potentially can interfere with visual acuity if this ingrowth is not arrested. Vessel ingrowth from the limbus proper can normally be anywhere from 0.5 to 1.5 mm, depending on the individual; it is very important to record the level of ingrowth at the time of the initial contact lens fitting in order to provide a baseline measurement. Abnormal ingrowth can exceed 3 mm of vascular development; clinical concern should be manifested by the 2.0 to 2.5 mm point. Steps to slow down or stop this process can include: fitting a new lens of increased Dk/L, refitting with a different category of lens material, changing the lens-care regimen, or simply reducing wearing time (Efron and Holden, 1986). However, recovery from this complication can be illusory. If contact lens wear is discontinued, the vessels will empty of blood, but the vessel walls remain intact, ready to immediately refill with blood if the initiating condition returns (i.e., reintroduction of the original contact lens conditions). Therefore, the importance of making the necessary corrective measures cannot be overstated.

Giant papillary conjunctivitis

Giant papillary conjunctivitis (GPC), a specific immunologic response of the posterior portion of the eyelids (the upper lid in particular) to the physical presence of a contact lens, has been known to interfere with the successful wearing of contact lenses on a long-term basis. The epithelial cells comprising the conjunctiva on the back surface of the upper eyelid tend to swell, causing the appearance of discrete bumps or papillae. Symptoms can include increased contact lens awareness, itching, and blurred vision. It has been stated that "the four key

etiological factors appear to be chronic hypoxia under the upper lid, mechanical irritation of the conjunctival surface due to lid-lens interaction, reaction to preservatives in solution, and an immunological reaction facilitated by environmental antigens harbored in lens deposits on the anterior surface of the lens" (Efron and Holden, 1986). A parallel between GPC and allergic or vernal conjunctivitis has been drawn (Allansmith, Baird, and Greiner, 1979) in that both conditions involve a basophil-rich delayed hypersensitivity. The prognosis for a full-blown case of GPC in the resumption of contact lens wear can be poor in that signs and symptoms can persist after years without lens wear. This will serve to be the greatest obstacle to any routine longterm contact lens wear program. Some studies have suggested that a change in contact lens material may help alleviate symptoms, but the clinical signs can still remain; in time the symptoms reappear, necessitating another change in lens material.

Superior limbic keratoconjunctivitis

A pattern of tissue disruption similar to that seen in GPC also can be detected on the superior bulbar conjunctiva and superior corneal epithelium underlying the upper lid. This clinical entity has been labeled contact lens induced superior limbic keratoconjunctivitis (SLK), and more often is associated with soft lenses than with rigid lenses. Causative factors are purportedly the same ones delineated for GPC (Rao, 1984; Efron and Holden, 1986). Although SLK appears to be an immunologic response, signs and symptoms will be alleviated with the discontinuation of lens wear, and follow the same pattern as GPC patients on resumption of lens wear.

Bacterial infection

A major ocular consideration related to contact lens wear is that of increased susceptibility to corneal infection. Estimates of the contact lens contribution to overall bacterial corneal infection rates range from 20 percent (Alfonso et al., 1986) to 70 percent (Omerod and Smith, 1986). Contact lens related bacterial corneal infections often are caused by gram-negative bacteria (Alfonso et al., 1986), which tend to be more destructive of corneal tissue. Methods to aggressively intervene with this potentially devastating sequela to contact lens wear must be pursued. The primary suspect in bacterial infection has been patient noncompliance with directed lens care procedures (Mondino et al., 1986); 82 percent of one sample (9 of 11) of corneal ulcer patients had not been properly caring for their lenses. However, 41 percent of an associated corneal ulcer sample (12 of 29) reportedly were caring for their lenses using appropriate procedures and materials, highlighting the idea that noncompliance may not be solely responsible for contact lens-associated keratitis. Consequently, efforts to fully understand

this condition's underlying mechanism should be pursued in order to improve intervention techniques.

Acanthamoeba infection

Corneal infection associated with contact lens wear also has been linked to organisms of the amoebae genus Acanthamoeba. While 83 percent of the Acanthamoeba-infected individuals in a recent retrospective clinical study were contact lens wearers, there was a strong indication that nonsterile water (home-made saline/swimming with lenses in place) had a key role in the infection process (Stehr-Green et al., 1987). Through June of 1988, 287 cases have been reported in the United States; based on this database, the three primary risk factors for Acanthamoeba keratitis are: history of corneal trauma, exposure to contaminated water, and contact lens wear (Stehr-Green, Bailey, and Visvesvara, 1989). While the trophozoite form of Acanthamoeba can be susceptible to several forms of disinfection, the encysted form is susceptible primarily to heat disinfection techniques only. However, the roles of the cyst and trophozoite forms within the infection acquisition and progression processes have not been delineated.

Detailed review of ocular considerations

Oxygen

The maintenance of normal corneal function is dependent on sufficient amounts of oxygen reaching the tissue (Fatt and St. Helen, 1971; Fatt and Linn, 1976; Polse, 1979). The clinical observation for compromised corneal function is corneal edema or swelling, and the thrust of many contact lens investigations has been toward determining the minimal level of oxygen necessary to avoid excessive corneal swelling. The underlying assumption is that a contact lens-wearing cornea exhibiting minimal to no edema is a normal cornea.

Oxygen is supplied to the anterior cornea via passive diffusion from the atmosphere by way of the precorneal tear film when the eye is open. Therefore, the normal amount of oxygen available to the tissue has a partial pressure of 159 mm Hg, since oxygen makes up 20.9 percent of the atmosphere and the normal atmospheric pressure is 760 mm Hg. When a contact lens is placed upon the cornea, the availability of oxygen can be reduced, causing corneal edema or swelling. The percent increase in corneal thickness can serve as an indicator of relative corneal health; a greater degree of corneal swelling would be indicative of a more severe physical insult. In addition, the longer the cornea takes to recover to a normal thickness after lens removal can be indicative of secondary underlying endothelial dysfunction.

Polymethylmethacrylate (PMMA) "hard" contact lenses, for all practical purposes, do not transmit oxygen. As a result, special fitting techniques are required to stimulate tear flow between the cornea and the contact lens, and therefore oxygen exchange, under the contact lens. Optimum fitting designs allow for a 10 percent tear exchange under the PMMA lens per blink (Fatt, 1969; Cuklanz and Hill, 1969; Fatt and Hill, 1970). Even with optimum design, the oxygen concentration under a PMMA lens after several hours wear can drop to about 3 percent, a level that is 1/7th the normal condition. The inescapable result is a certain degree of corneal swelling. It is this swelling that is responsible for rebound corneal parameter changes (e.g., spectacle blur, induced astigmia) when PMMA lens wear is discontinued.

In an effort to get more oxygen to the cornea, oxygen transmitting plastics have been utilized for contact lens applications. The most extensively fit lenses have been the hydrophilic, "soft" contact lenses. These lenses are fit larger than the diameter of the cornea, so that there is little lens movement on a blink. This provides both lens stability and lens security from foreign body intrusion (properties PMMA lenses lack). While the oxygen supply to the cornea occurs by direct transmission through the contact lens, there is still a reduction in oxygen availability. There is also little rejuvenation of the postsoft contact lens tear layer, with only a 1 percent tear exchange rate per blink (Polse, 1979; Wagner, Polse, and Mandell, 1980). Whether this tear stasis or stagnation has any major importance is unclear and is only recently being specifically investigated. However, the presence of minute epithelial defects, termed microcysts, has been suggested to represent an extracellular accumulation of metabolic byproducts trapped within the deeper aspects of the epithelium, a chronic metabolic stress result (Zantos, 1984).

New polymerization processes have led to the development of rigid, gas permeable (RGP) contact lenses. Oxygen permeability in RGP lenses is obtained by the chemical polymerization of silicone and/or fluorine with PMMA. Oxygen transmissibility of these materials can exceed that of soft lenses. Silicone lenses thus far have the highest oxygen permeability, and apparently cause less corneal swelling when worn during sleep than with no lens on the eye (Sweeney and Holden, 1987). A recent paper provides a physical explanation for this phenomenon (Refojo, Koch, and Leong, 1989). If an individual experiences incomplete eye closure during sleep with silicone lenses in place, then the superior oxygen transmissibility properties of these lenses can permit oxygen to be readily dispensed through the lens and across the cornea to a degree beyond that available in an incompletely closed nonsilicon lens-wearing eye.

Even with advanced lens technology, corneal hypoxia is still an issue of concern. Numerous studies have sought to establish

the minimum amount of oxygen availability required to avoid corneal insult. The more the question has been studied over the years, the greater have been the estimates. Early estimates of tolerable hypoxia used gas infused goggles to create an exposure to artificially low oxygen levels for 1.5 hours (Polse and Mandell, 1970); below a critical level of 2.5 percent oxygen (partial pressure of 19 mm Hg) the corneas of experimental subjects reacted with increased hydration or edema. A similar study (Mandell and Farrell, 1980) established the minimum oxygen requirement for the avoidance of corneal swelling to be at least 3.02 percent (equivalent to a partial pressure of 23 mm Hg). A later study (1984) by Holden, Sweeney, and Sanderson suggested the above values were insufficient for the maintenance of normal corneal function. Their results indicated the minimum precorneal oxygen tension to avoid corneal edema to be at least 10.1 percent (an oxygen tension of 74 mm Hg). Holden and Mertz (1984) more specifically stated that while a daily lens wear regimen requires 10.1 percent oxygen, an extended lens wear regimen carries a minimum oxygen requirement of 17.1 percent in order to avoid corneal swelling beyond normally encountered physiological levels.

More recent work, monitoring corneal oxygen uptake rates (Benjamin, 1986), has suggested that 18 percent oxygen (137 mm Hg) represents the minimum value for normal corneal function, although corneal swelling is not evident at 18 percent oxygen. This last finding suggests the clinical method of assessing loss of normal corneal function (i.e., corneal thickness) may be an inadequate measure. Finally, the authors of yet another article (Efron and Brennan, 1987) have suggested the critical oxygen requirement of the cornea is that which is normally available from the natural environment (20.9 percent).

Ocular surface pH issues

Attempts at quantifying the normal tear pH value have yielded varying results. Although one cause of variation appears to be due to instrumentation differences, the primary cause of variation appears to be the location or source of the tear sample. In the past, the tearfilm has been approached as a unitary entity independent of whether a sample or pH reading was obtained from the fornix, cul-de-sac, inferior meniscus, or limbus. Efforts at documenting the pH of the precorneal tearfilm (i.e., that canopy of mucin, aqueous, and oil directly anterior to the cornea) have obtained a mean value range of 7.45 to 7.83, shown in Table 1 (Carney and Hill, 1976; Abelson, Udell, and Weston, 1981; Fischer and Wiederholt, 1982; Coles and Jaros, 1984; Norn, 1988; Andres et al., 1988; Chen and Maurice, 1990). Since measurements of precorneal tearfilm pH under the extended open-eye condition have been shown to match that predicted by CO_2 equilibration calculations (Fischer and Wiederholt, 1982), it is likely these values are very close to the true precorneal tearfilm pH.

Accepting previous reports of pH decrease/CO_2 trapping or buildup under hydrogel lenses (Holden, Sweeney, and Vannas, 1985, and Holden, Ross, and Jenkins, 1987; Chen and Maurice, 1990), combined with reports of normal tear pH at the anterior lens surface, it is possible a pH gradient is obtained within the matrix of a hydrogel lens. Moreover, this internal gradient, bordered by distinctly different pH environments at each hydrogel lens surface, would preclude a lens from being considered as simply a unitary piece of plastic. It previously has been shown soft lens hydration is directly influenced by the pH of its solution (McCarey and Wilson, 1982). Therefore, a lens in close approximation with a cornea, with differing pH solutions at each surface could have a transitional water content from one surface to the other. Consequently, there would be a varying index of refraction, as well. This varying pH gradient then would create a layer of "lenses" within the physical confines of the physical anterior and posterior lens surfaces (Figure 1). This laminar arrangement of varying water content and refractive indixes could be responsible for the optical issues linked to certain contrast sensitivity deficits of hydrogel lens wear (Woo and Hess, 1979; Bernstein and Brodrick, 1981; Grey, 1986).

Table 1.
Recent tear pH studies.

Author(s)	Year	Location	Instrument	N (subjects)	Mean+/- SEM
Norn	1988	Inferior fornix	Microglass electrode	41	6.93+/-0.24
Coles and Jaros	1984	Lateral fornix	Direct contact microelectrode	133	7.11+/-1.50
Fischer and Wiederholt	1982	Limbus (1 o'clock)	Micro-pH electrode	4	7.60+/-0.09
		Limbus (5 o'clock)	Micro-pH electrode	4	7.50+/-0.08
Abelson et al.	1981	Inferior cul-de-sac	Microcombination glass pH probe	44	7.00+/-0.20
Andres et al.	1988	Precorneal	Micro-pH electrode	71	7.51+/-0.18
Carney and Hill	1976	Meniscus	Microelectrode	16	7.45+/-0.16
Chen and Maurice	1990	Precorneal	Fluorescent probe	6	7.83+/-0.10
Lattimore	1990	Precorneal	Self-referenced pH electrode	28	7.43+/-0.06

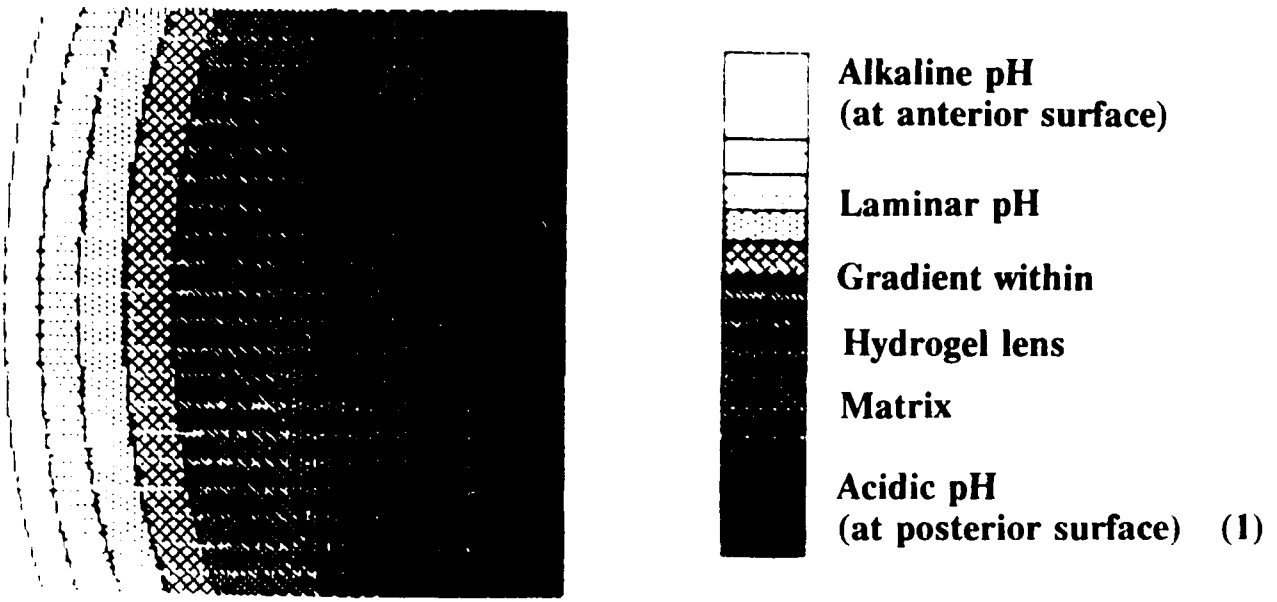


Figure 1. Proposed hydrogel matrix pH gradient.

Epithelial morphology

Both soft and rigid contact lenses have been implicated in corneal epithelial thinning. This thinning occurs by two processes: premature loss of superficial squamous cells, and the physical compression of the remaining wing and basal cells (Bergmanson and Chu, 1982; Bergmanson, Ruben, and Chu, 1985; Bergmanson, 1989). The significance of this thinning is unknown; however, it is important to note normal overall corneal integrity may be dependent on the presence of a healthy epithelium (Lattimore, 1988). Therefore, contact lens induced epithelial thinning may be of major consequence for the deeper layers of the cornea, and may have a direct contribution to stromal and endothelial changes that have been documented in the literature.

Corneal metabolism

A number of studies have documented singular aspects of contact lens induced changes in corneal metabolism. Epithelial glycogen depletion has been shown to occur with contact lens wear (Smelser and Chen, 1955; Burns and Roberts, 1970; Thoft and Friend, 1975). The mechanism for this depletion of glycogen secondary to the stress of contact lens wear is not clear since other metabolite assays were not applied to the same tissue samples. In contrast, it has been suggested that the normal glucose supply is sufficient for the epithelium, even under completely anoxic conditions (Riley, 1969; Thoft and Friend, 1971); therefore, glycogen mobilization should not be necessary. This incongruity has not been explained.

Another metabolite study has shown increased lactate in the corneal stroma accompanying contact lens wear (Klyce, 1981). It was theorized this lactate accumulation was responsible for contact lens induced stromal edema by osmotic pressure. However, if the source of increased lactate is the corneal epithelium, this theory does not explain how the accumulated lactate, and edema, build in a posterior to anterior fashion in the stroma. Again, paired metabolite assays were not performed, so a comprehensive picture of the contact lens-simulated metabolic shifts was not obtained.

Endothelial morphology

The typical corneal endothelial layer mosaic, consisting of cells of similar shape and equal size, may be altered so the monolayer is transformed into a variety of cell shapes (pleomorphism) and a variety of cell sizes (polymegethism). Although only a relatively recently documented phenomenon, polymegethism has been reported in wearers of nearly all types of contact lenses except those wearing the silicon elastomer (Schoessler, 1983; Snyder, 1982; Schoessler, Barr, and Freson, 1984; Stocker and Schoessler, 1985). It should be pointed out variations in cell shape and size can exist without a decrease in cell density (Schoessler and Woloschak, 1981). An endothelial assessment is performed using specular microscopy, combined with computer analysis of photographs of the central endothelium to determine mean cell area and density, standard deviation of the cell area, and maximum cell area/minimum cell area ratio. Holden, Sweeney, and Vannas, (1985) monitored the corneal endothelium of subjects fitted with extended wear contact lenses, and found an increase in the cell size variability within 2 weeks of the start of lens wear, with little to no recovery of the cell size distribution after discontinuance of lens wear.

Endothelial function

Initial studies of the corneal endothelium examined physical changes only; subsequent investigations have attempted to link physical changes with functional alterations. In Holden's laboratory (Sweeney, 1985) thick hydrogel lenses, combined with eye closure for 2 hours, were used to induce moderate corneal edema in subjects with polymegethism. The level of induced corneal edema correlated with the degree of polymegethism, plus the rate of deswelling had an inverse correlation with the degree of polymegethism. Other studies also have suggested the functional capacity of the endothelial pump mechanism might be correlated with morphological appearance; patients who displayed corneal endothelial polymegethism prior to cataract removal and intraocular lens implantation had significantly greater postsurgical corneal edema when compared to their homomegethous counterparts (Rao et al., 1979; Rao, 1984, and Rao et al., 1984).

O'Neal and Polse (1985) found a significant correlation between the degree of polymegethism and the rate of recovery from an induced corneal edema; along with this they found age-related changes in both endothelial morphology and function.

It has been proposed that corneal hypoxia represents the underlying cause of contact lens induced polymegethism (Schoessler and Woloschak, 1981; Schoessler, 1983; Hirst et al., 1984; Stocker and Schoessler, 1985). Contact lenses have been found to decrease the level of oxygen dissolved in the aqueous in animals (Barr and Silver, 1973; Stefansson, Wolbarsht, and Landers, 1983; Stefansson, Foulkes, and Hamilton, 1987). This condition presumably places the endothelium in a hypoxic environment. The implication of these studies is that a hypoxic endothelium is subject to polymegethous morphological changes, as well as the functional changes paired with it. The precise physiological mechanism of how corneal hypoxia induces polymegethous changes has not been determined. Possible mechanisms include: an accumulation of carbon dioxide, an accumulation of lactate, a pH change, and/or a change in ATP and calcium ion concentrations (Barr and Schoessler, 1980; Schoessler and Woloschak, 1981; Caldwell et al., 1982; Schoessler, 1983; Schoessler, Barr, and Freson, 1984; Zagrod and Connor, 1988).

Generally, it has been assumed that alteration of the cell shape serves to inhibit the endothelial pump function. However, it may be possible that inhibition of the endothelial pump function is what alters cell shape. Indeed, ionic flux changes, combined with the increased presence of water, might reasonably be expected to alter cell shape. Transient corneal endothelial mosaic changes have been recorded within minutes after placing contact lenses on the eyes of unadapted patients (Zantos and Holden, 1977; Barr and Schoessler, 1980; Kamiya, 1982). An immediate response is indicative of a metabolic shift of some sort. As a result, it's certainly possible specific metabolite assays could be used to determine the mechanism responsible for polymegethous changes.

Summary statement

Based on the volume and detail of available operational evidence, contact lenses appear to have a valid place in the military aviation environment. However, factors not considered in this review must be appraised. Not everyone can obtain clear and comfortable vision while wearing contact lenses. Also, a consistent and reliable bifocal contact lens is not yet available, although some promising concepts are under civilian study. Since the most accomplished aviators are often times matured into presbyopia, a significant portion of the military's most highly skilled pilot population would not be correctable with contact lenses. Last, a number of physiological,

biochemical, and clinical issues associated with contact lens wear have yet to be resolved. Consequently, contact lenses likely represent only a partial solution to spectacle incompatibility problems. Only a coordinated, multidisciplinary approach to systems development will provide the final combination of elements necessary for long-term success in dealing with optical compatibility issues.

In conclusion, regardless of the type of lens, a contact lens wearing cornea either exhibits, or has the potential for developing any number of physiological, biochemical, and/or pathological changes. These apparently have been considered to be of minor significance by the general civilian health care community, as evidenced by the proliferation of the contact lens industry. However, if the military is to become actively involved in the provision of contact lens care to its aviators, then it is imperative that a comprehensive clinical and scientific database be established. The objectives of future investigations should be to document both the corneal changes that can be induced by contact lens wear and the operational aspects of contact lens wear by military aviators. These are required in order to permit the military leadership to make a fully informed decision based on a complete understanding of the benefits and deficiencies of this form of visual correction.

Materials and methods

Subjects

Ametropic aircrewmembers were identified by their brigade flight surgeon for possible inclusion in the study. It was initially estimated that a total sample of 400 ametropic aircrew would be obtained. Potential subjects were provided with an informed consent briefing by a representative from USAARL; a medical history was obtained immediately following the informed consent briefing to ensure medical acceptability. Exclusionary conditions included a history of:

1. chronic/acute inflammations of the anterior segment of the eye.
2. disease processes affecting sclera, conjunctiva, or cornea.
3. systemic disease affecting the anterior segment of the eye.

Those found eligible were further briefed on the study; salient risks and potential benefits were carefully explained. It was stated that lens wear could not be continued by the subject after the study had been terminated, unless contact lens wear was adopted as a routine clinical program following the

conclusion of the study. Each eligible individual was given an opportunity to volunteer for or to reject participation in the research project. Those individuals volunteering were requested to read and sign a Volunteer Agreement Affidavit (Appendix D), and a Volunteer Registry Data Sheet (Appendix E). Detailed plans for scheduled followups were coordinated with the subject, the subject's unit, and USAARL/contract investigation teams.

Medical personnel and facilities

Professional requirements

A contact lens fitting team, comprised of two experienced optometrists and one technician, under task order contract to USAARL were responsible for most examinations. A USAARL research optometrist and two technical assistants were also involved at the specific locations of Fort Rucker, Fort Bragg, Fort Riley, and Fort Campbell. The USAARL personnel were additionally used as a temporary backup, when the contract team suffered a transient personnel shortage. Ten two-man teams of active duty Army optometrists and eye technicians were involved in exams associated with Desert Shield/Storm deployments. Four of those teams deployed to Saudi Arabia to provide on-site care, consultation, and evaluation of deployed subjects.

Brigade and other designated flight surgeons responsible for the routine health care of aircrewmembers were actively involved in the operational aspect of the study as field medical monitors in seeking individual assessments of contact lens effectiveness on a daily basis. Selected flight surgeons received 1 month of training, at the Army Medical Center level, in order to provide a general background necessary for the recognition of common contact lens-related complications. Detailed briefings at annual flight surgeon continuing education meetings (USAREUR, OAP, ASMA) were provided by USAARL personnel as an additional means of keeping the "field" up to date.

The optometrist(s) located at regional health care facilities were briefed on the investigation in the event primary medical support was required. This was coordinated through OTSG, HSC, and 7th Medical Command (MEDCOM) Headquarters. Detailed briefings at annual optometric continuing education meetings were provided by USAARL personnel as an additional means of keeping the "field" up to date.

The ophthalmologist(s) located at regional health care facilities were briefed on the investigation in the event tertiary medical support was required. This was coordinated through OTSG, HSC, and 7th MEDCOM Headquarters.

Technical support

As part of the contract team, a qualified technician was utilized in the initial fitting of the lenses, as well as during all other examinations. Two USAARL technicians also were available for additional assistance in certain instances.

Facilities

Regional eye care facilities were used for all examinations, scheduled followups and unscheduled follow-ups. Regional eyecare personnel were not involved in scheduled fittings and followup examinations. However, they were available for individual subject consultation between scheduled visits, as desired.

Medical equipment

The following equipment was used in scientific control of data collection:

Phoropter with stand, examination chair, and projector.
Automated keratometer with automated refractor
Biomicroscope
Objective automated refractor
Aesthesiometer
Ultrasound Pachometer
Endothelial camera
Nanoliter osmometer
pH meter
Micropolarographic electrode

Lens materials

Extended wear contact lenses were utilized in this study. In general, soft lenses can be of either low (25-35 percent), medium (35-60 percent), or high (60-85 percent) water content, and can be made of either an ionic copolymer or a nonionic polymer. Two types of soft lenses were used in this study: a medium/high water content lens and a low water content lens. Rigid gas permeable (RGP) lenses were used [as backups] for hyperopic and highly astigmatic subjects. All soft lenses were disposed of on a weekly basis. RGP lenses were worn on a weekly basis. However, these lenses were cleaned and disinfected weekly, and reinserted after at least one night without lens wear. RGP lenses were replaced at the quarterly followups. A new soft lens supply was furnished at each quarterly followup, as well. All materials (i.e., lenses and solutions) were commercially available and approved by the U.S. Food and Drug Administration (FDA). The protocol was determined not to be an

original use of contact lenses, since the Federal Aviation Administration (FAA) does not restrict the use of contact lenses by civilian pilots.

Since the soft lens system was disposable, soft lens disinfection and cleaning solutions were not needed. Comfort solutions, available through an independent manufacturer, were provided to the subjects, as were weekly replacement lenses. The comfort solution of choice was "Lens Plus Rewetting Drops" by Allergan Pharmaceuticals*. The advantages of this lens lubricant were its being preservative-free and packaged in boxes of 30 single-use 0.01 ounce vials; the container was discarded after each use. Employment of this product bypassed potential problems related to reusable bottle contamination issues and preservative-induced toxic and hypersensitivity reactions. RGP lenses required the use of cleaning and conditioning solutions that were specifically formulated for the RGP lenses being used. All solutions were provided to each subject on a quarterly basis.

Procedures

Initial examination and fitting

Ametropic aircrewmembers who volunteered and were selected for the study were seen individually on an appointment basis. Once an acceptable initial fit was achieved, subjects were given instructions by a technician concerning lens insertion, removal, and care. At that time, the subject also was instructed on symptoms which might necessitate lens removal and/or unscheduled professional care. A written summary of essential information was provided for each participant to keep. The aviation brigade flight surgeon served as a point of contact for followup appointments and additional consultation, if needed. Each subject was given a wallet-sized medical identification card specially designed for contact lens wearers. The subjects were instructed that this card (Appendix F) should be prominently displayed in their wallet and would serve to alert medical personnel that the individual was wearing contact lenses should he be incapable of relating such information. Additional medical alert methods (dog-tag identifiers, bracelets, etc.) could be applied at the individual discretion of each subject and/or local flight surgeon.

Followup examinations

Followup examinations were performed at 24 hours, 7 days, and 3 months postfitting. Thereafter, all followup examinations were on a quarterly basis. Additional eyecare visits and/or

* See list of manufacturers.

consultations could be initiated by the subjects through their flight surgeon to the regional eyecare facility should unscheduled followup be required.

Wearing schedule

Upon completion of the initial fitting session participants were instructed to begin continuous wear immediately. The subject were required to return for a 24-hour evaluation; during the initial 24-hour period the subject was restricted to duty not to include flying (DNIF). After the 24-hour exam, the newly dispensed lenses were to be worn without removal for 6 more days. The flight surgeon issued an "up-slip" once the 24-hour exam was completed and after confirming that visual acuity met AR 40-501 standards (i.e., 20/20 or better Snellen visual acuity in each eye with contact lenses in place). On the seventh day, the subject returned to the exam facility for additional evaluation. At the successful conclusion of this evaluation, a 3-month supply of lenses was issued. Appropriate amounts of comfort drop solutions were dispensed at each session, as well. The lenses were worn continuously for a maximum of 7 days. On the evening of the last day of lens wear, the soft lenses were removed and discarded. The RGP lens wearers removed their lenses and performed the required lens cleaning and disinfection procedures; the lenses then were stored overnight in a provided storage case. The subject then would sleep that night without any lenses; on rising the next day, the subject applied either a new pair of soft lenses or the cleaned RGP lenses. The subjects were instructed that if they must remove a soft lens for any reason (i.e.: foreign body sensation, mild irritation), the lens should not be reapplied. Instead, a new lens should be applied, and the old one disposed of. It was permissible for RGP lenses to be removed, cleaned, and reinserted. Subjects were advised that should the irritation/discomfort continue, the local flight surgeon should immediately be consulted. It was stressed that in no case should a subject sleep with a contact lens on an irritated eye; when in doubt of ocular health, the subjects were advised to immediately seek medical assistance.

Data collection

A complete data record was chronicled during each exam (initial, followups) for all subjects. Standardized data collection forms were used throughout the course of the study. The contractor developed a database, and provided all data to USAARL investigators in both hard copy and organized floppy disk format. Ultimately, three separate databases were maintained: local Fort Rucker subjects, worldwide protocol subjects, and Desert Storm subjects. There was some overlap in the databases

since a number of people fell in all three groups over the course of the overall investigation. Quanlitative data can be found in Appendix G and quantitative data can be found in Appendixes A and B.

Eye-related symptoms and medical emergencies

When a subject developed an adverse ocular sign or symptom, or sustained an eye injury, he was instructed to contact the unit flight surgeon immediately. Special instructions were provided to these flight surgeons regarding identification, treatment, and disposition of these subjects. This consisted of a supervised 4-week clinical experience in a MEDCEN Ophthalmology Clinic, coordinated through the Ophthalmology Consultant to The Surgeon General of the Army.

Subjective assessment procedures

A self-administered questionnaire was used to obtain subjective information from the participants at the quarterly followups; some questions were asked only at the first quarterly followup, others were repeated at each followup. The questionnaire addressed user acceptability, job performance impact, problems encountered, medical services, and training. In addition, there was some objective observation time in AH-64 simulators for performance assessment under contact lens/ spectacle-wear conditions by unit flight surgeons and USAARL investigators. These data, in addition to the flight surgeon obtained interview/debriefing data, were used in assessing the operational impact of contact lens wear.

Lens physical assessment

Sample used lenses, obtained at scheduled followup exams, were returned to USAARL for examination for any physical defects, transmittance/absorbance analysis, and for protein deposit determination.

Medical support data

Information related to medical resources and logistical requirements to support contact lenses in the field were documented throughout the course of the study. Records of all materials consumed were maintained as an embedded part of the data collection form, and were therefore extractable from the computerized database for interim and final report purposes. Incidence of health facility visits, diseases, and injuries were logged as well.

Experimental design/data analysis

This study was designed to assess the feasibility of contact lens wear as an option to spectacle wear for ametropic Army aircrewmembers. The primary objectives were to characterize the physiological/biochemical response of the cornea to contact lens wear, and to identify the strengths and weaknesses in contact lens wear associated with the occupational tasks and environmental conditions unique to the Army aviation environment. Experimental data were obtained through the use of objective clinical scientific evaluation techniques, subjective questionnaires, and informal interviews concerning operational flight performance. Data analysis consisted of simple descriptive statistics and analysis of variance procedures. Specific factors of interest were type of contact lenses worn, geographical location of unit, and type of aircraft flown. The data sheets provided in Appendixes A and B indicate the dependent variables of interest. Civilian studies served to provide control data for interpreting clinical findings. It was anticipated that with the acquisition and analysis of this information, the military community would be able to make an informed decision regarding the long-term feasibility of utilizing ametropic aviators in advanced attack helicopter systems.

Human use justification

The experimental question related to the practical application of contact lenses to a specific military environment. As such, an animal model simulation was not able to provide practical information regarding the subjective strengths and weaknesses of contact lens wear.

Regulation compliance

This protocol was in compliance with:
- AR 70-25, Use of volunteers as subjects of research.
- USAMRDC Regulation 70-25, Use of human subjects in research, development, testing and evaluation.
- USAARL Policy 70-3.

Health and safety of volunteers

Risks

The salient risks of wearing extended wear contact lenses (both soft and rigid) were presented in the volunteer briefing, and are detailed in the next paragraph. The ophthalmic examination procedures were standard, accepted techniques commonly utilized in the field of contact lens practice and research. Performance evaluation was not intended to interfere

with the individual's or unit's normal training activities. However, it was necessary for each unit to give followup exam appointments top priority for this program to succeed.

The chief source of risk to participants in this study was the possibility of an accident resulting from the actual wearing of contact lenses in the performance of military flight and other duties. The wearing of extended wear soft contact lenses has in the past been associated with the following effects:

a. Minor, temporary risks that are usually not serious and do not last very long.

    a. Mild watering of the eyes.
    b. Mild sensitivity to light.
    c. Temporarily blurred vision.
    d. Slight redness of the eyes.
    e. Faint sensation of dryness of the eyes.
    f. Mild feeling of irritation to the eyes.
    g. Mild eye pain.
    h. Slight swelling of the cornea or eyelids.
    i. Discomfort/reduced vision due to a foreign body, displaced lens, or lens drying.

b. Serious and possibly permanent risks.

    a. Abnormal growth of blood vessels into the cornea.
    b. Scarring of the cornea.
    c. Subtle changes in the cornea which reduce vision.
    d. Eye infections, possibly leading to surgical replacement of the cornea, or loss of an eye.
    e. Decreased corneal capacity to cope with fluid buildup, which can lead to surgical replacement of the cornea, or loss of the eye.

c. Based on preliminary studies, in-flight risks for a standard flight profile were judged to be minimal. However, as a safeguard, primary aircraft operators were instructed that they were not to fly with another contact lens wearing subject or copilot; this requirement was also documented on the formal waiver, which required both commander and individual signature. Backup spectacles were carried at all times, in case lenses had to be removed while performing actual flight duties.

Medical safeguards

This project was been planned for maximum safety and the volunteer subjects were closely monitored by eyecare professionals. Many procedures were built in to ensure the safety of study participants. These safeguards included:

1. Thorough eye examinations on a regular schedule.
2. Contact lenses were not prescribed if deemed medically unsuitable.
3. Training was provided in the safe use and care of the lenses.
4. Lenses were replaced on a periodic basis.
5. Contact lens wear was temporarily suspended if medically indicated.
6. Participation was discontinued if medically indicated.
7. The local flight surgeon was an integral part of the investigational team, and was appropriately trained in the recognition of common contact lens related complications, and was the initial point of contact in the event of an adverse incident.
8. Regional medical personnel (optometrists, ophthalmologists, and emergency room personnel were briefed on the project in case of a medical emergency.

Medical monitor

The protocol medical monitor was board certified in ophthalmology. The field medical monitors for this study were the unit flight surgeons normally responsible for the health care of the subjects at their regular aviation medicine clinic or TMC.

Individual privacy and handling of data

Other than the flight waiver, only information arising from serious medical incidents was placed in the individual's medical record. All research data files were kept in the strictest confidence in accordance with regulations. Raw data forms and computer files have had limited access and are used for research purposes only. No individual information was released without expressed written consent from the subject or other recognized authority.

Results and discussion

Introductory description

General technical report

A total of 582 aircrew members participated as contact lens-wearing subjects. The Armywide AH-64 portion had 238 subjects,

while the Desert Shield/Storm portion had 344 subjects. Overall, there were 868 volunteers for both portions of the study. Therefore, the comprehensive fitting success rate was 72 percent (582/868). Forty-two subjects withdrew or were discontinued because of poor physical fit and/or unsatisfactory visual acuity. All unsuccessful fits and withdrawals were essentially a function of presbyopia, moderate to high astigmatism, and extreme corneal curvatures. This left a 67 percent wearing success rate of the original 868 volunteers; and of those successfully fitted with lenses this represents a 93 percent wearing success rate.

Since Army aircrew are subject to a form of screening via the initial entry flight physical standards, many of the ametropes exhibited low visual corrections compared to the general spectacle-wearing population. A display of spherical refractive errors for all 582 subjects can be seen in Figure 2. The refractive error distribution of these subjects peaked at -0.75 diopters (D), which is considerably less than the civilian spectacle-wearing population distribution peak near -3.50 D. A comparison histogram between the Desert Storm and the AH-64 subjects also was established (Figure 3). Using a nonparametric,

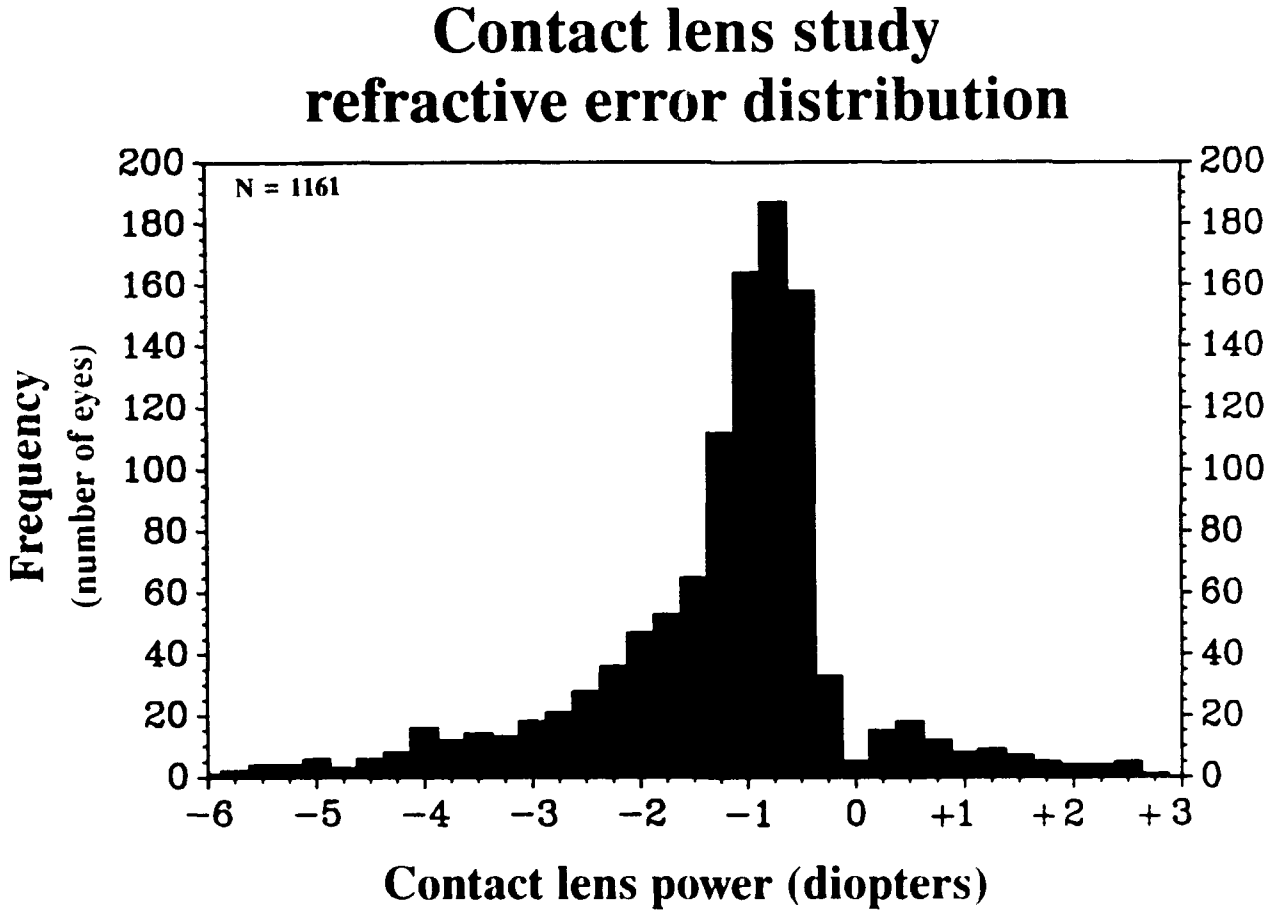


Figure 2. Contact lens study refractive error distribution.

discrete variable analysis for subject ages, the two samples were found to not be statistically different (p=0.54). Therefore, this refractive error distribution pattern likely describes that of the overall ametropic Army aviation population.

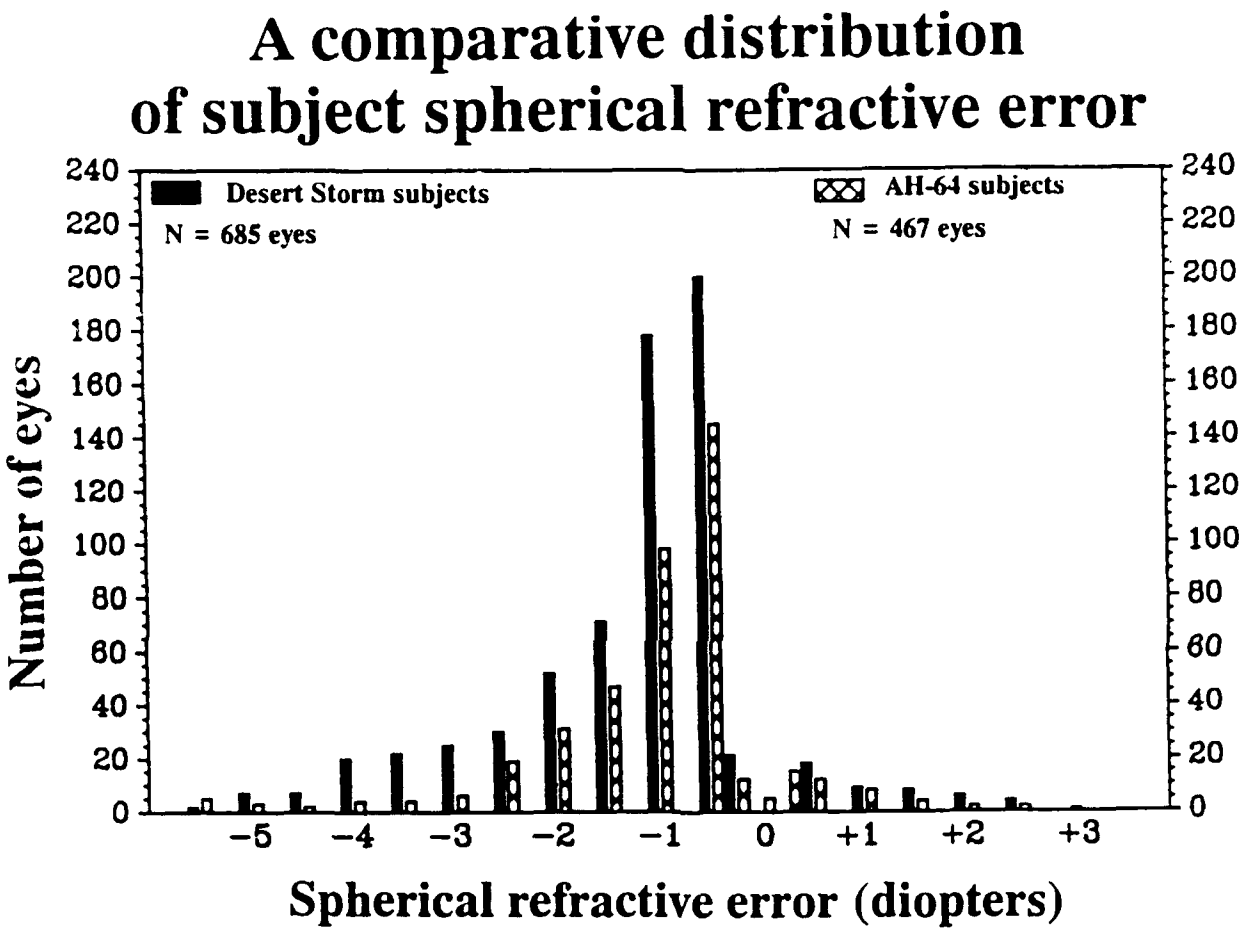


Figure 3. A comparative distribution of subject spherical refractive error.

Slit lamp examination

Clinical evaluations were done on a quarterly basis. Specific physical and physiological issues are addressed independently in other sections of this report. However, selected slit lamp exam results are presented here as a part of discussions on general clinical issues. There were no significant changes over time in terms of gross physical

appearance of the eyes. Qualitatively, the bulbar and palpebral conjunctiva could be described as slightly chemotic and hyperemic in the typical subject (more so in the soft lens wearers than the RGP wearers). However, this was not statistically demonstrable.

The relative distribution of lens types used reflected the fitting methodology. Since the 58 percent water content lens was the lens of initial choice, that lens was worn by the majority of subjects. The 38 percent lens and RGP lens were backups in the event the initial lens did not provide an adequate fit or satisfactory vision. Consequently, the 38 percent and RGP lenses were used less frequently (Figure 4). The ages of the subjects ranged from 18 to 46 (Figure 5). The bimodal distribution pattern was of some concern, so the Aviation Epidemiology Data Register (AEDR) was probed for the age of all Army aviators. A

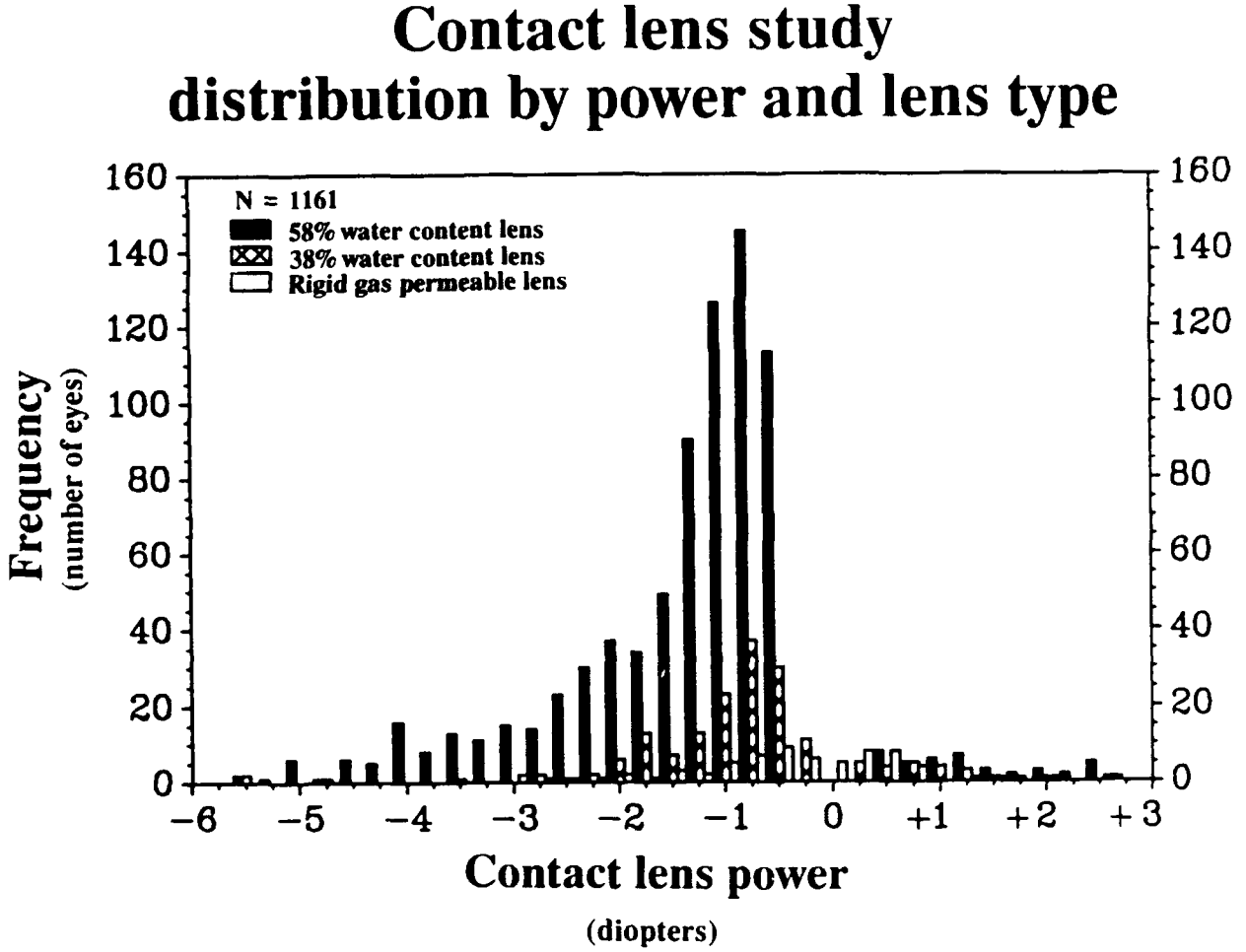


Figure 4. Contact lens study: distribution by power and lens type.

similar bimodal pattern was evident (Figure 6); therefore, our sample is shown to be representative of not just the ametropic population, but also of the aviation population in general.

Lens costs were a reflection of manufacturer materials and techniques. The 58 percent lenses cost $320/person/year; the 38 percent lenses cost $740/person/year; the RGP lenses cost $215/person/year. RGP care kits were $200/person/year and wetting solution for soft lenses cost $95/person/year. Mean wearing time was 4.4 days for soft lens wearers by questionnaire. Verbal discussion confirmed that, prior to Operations Desert Shield and Storm, subjects typically wore their soft lenses during the 5-day garrison work week, taking weekends off. The RGP lens wearers never got beyond a 2-day/1-night schedule primarily because of difficulties adapting to lens edges and thickness. During the Southwest Asia deployment, subjects were provided with enough lenses to adopt a 3-day wearing schedule.

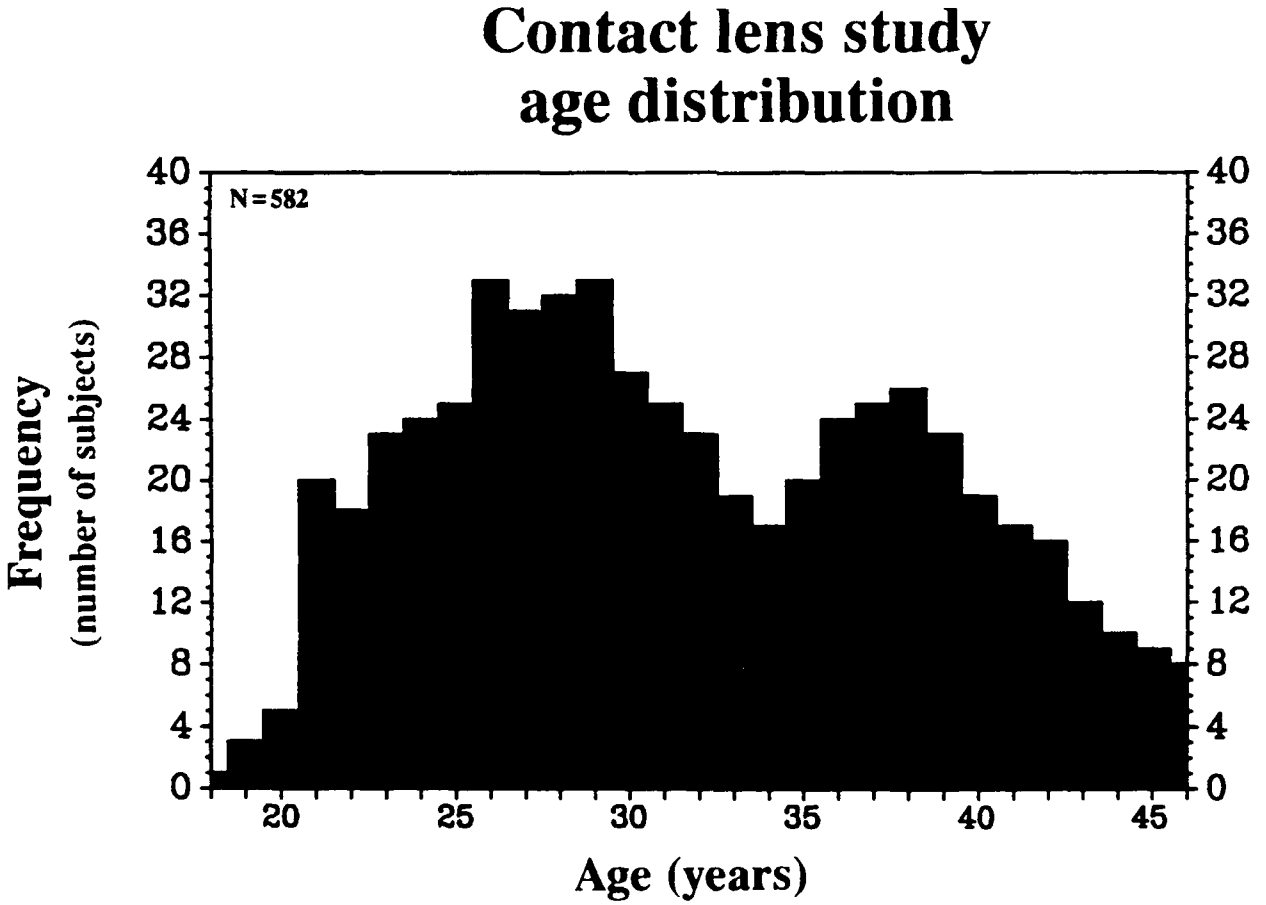


Figure 5. Contact lens study: age distribution.

Most reported adhering to that regimen. However, during the combat phase wearing time increased as a function of field conditions and operational intensity.

Limbal evaluations were negative in terms of inflammation and associated clinical significance, but assessments of limbal vascular development over the course of the study were nevertheless statistically significant ($p<0.001$). Limbal vascularization scores, as a function of quarterly examination, increased throughout the time course of the study (Figure 7). Regional comparisons of limbal vascularization revealed no change in the nasal and temporal quadrants ($p=0.17$ and 0.31, respectively); vascular progress in the superior and inferior quadrants was statistically significant ($p<0.0001$ for both). Since those limbal areas already are impinged upon by the eyelids, hydrogel effects would compound those already hypoxic

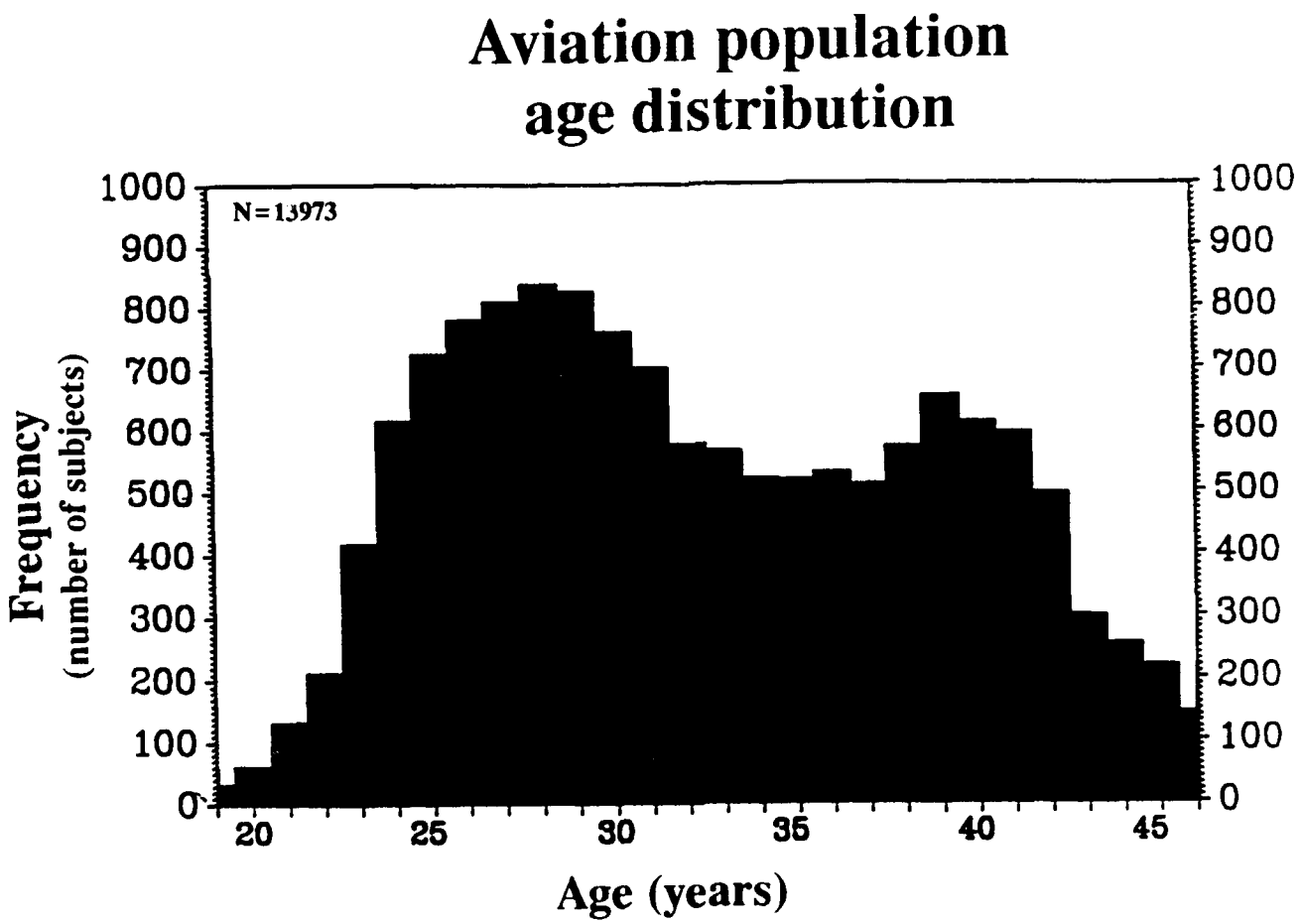


Figure 6. Aviation population age distribution.

areas. These areas of the limbus should therefore serve as the most sensitive indicators of hydrogel lens-induced corneal stress. A breakout of scores by lens type revealed the RGP lenses to have been stable over time, while the soft lenses were not. Therefore, the overall effect was a reflection of soft lens wear only.

Evaluations of conjunctival and corneal epithelial surface integrity were done with both rose bengal and fluorescein stains (Figure 8). The rose bengal failed to detect significant devitalization of corneal tissue, but a significant amount of bulbar conjunctival devitalization was manifested. This was particularly so in the inferior region, but could be seen in all quadrants. The subjective impression was that the soft lens acted somewhat as a sponge, drawing moisture from adjacent conjunctival tissue. Over the course of the study, mean rose

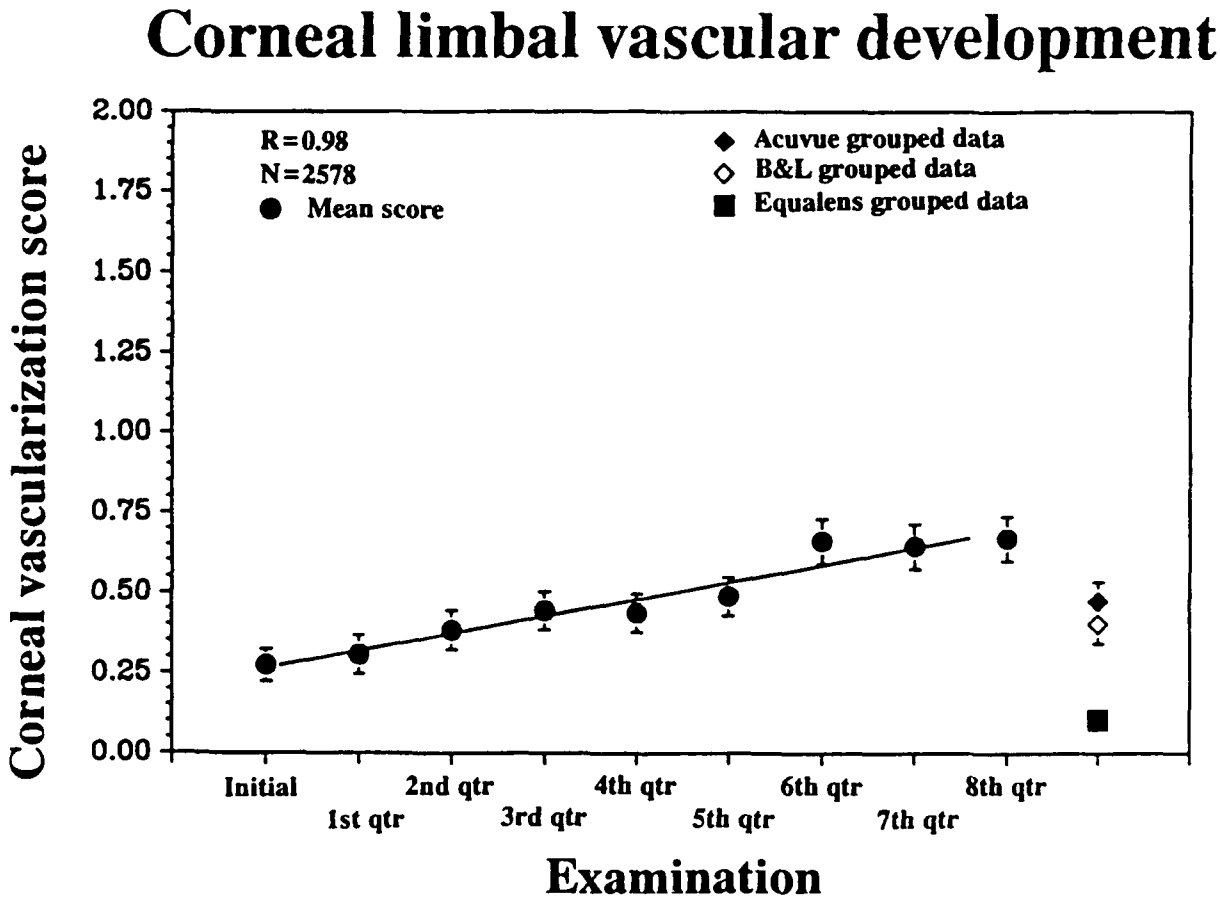


Figure 7. Corneal limbal vascular development.

bengal stain severity score did not change. However, it did initially change as a function of duration of extended wear of the pair of lenses currently being worn (Figure 9).

While fluorescein uptake was seen conjunctivally, most often it was associated with a break in the corneal epithelial barrier seen as punctate staining (Figure 8). The vast majority of these observations were associated with fine, scattered punctate staining that was graded at level 1 or 2 on a 0-4 scale. Again, the subjective impression was of a contact lens-induced tissue water or moisture loss. As with rose bengal, mean fluorescein severity score did not change over the course of the study. However, it did change as a function of duration of extended wear of the lenses currently being worn (Figure 10).

Figure 11 emphasizes the differences between the two stain mean score curves. While rose bengal-documented cell

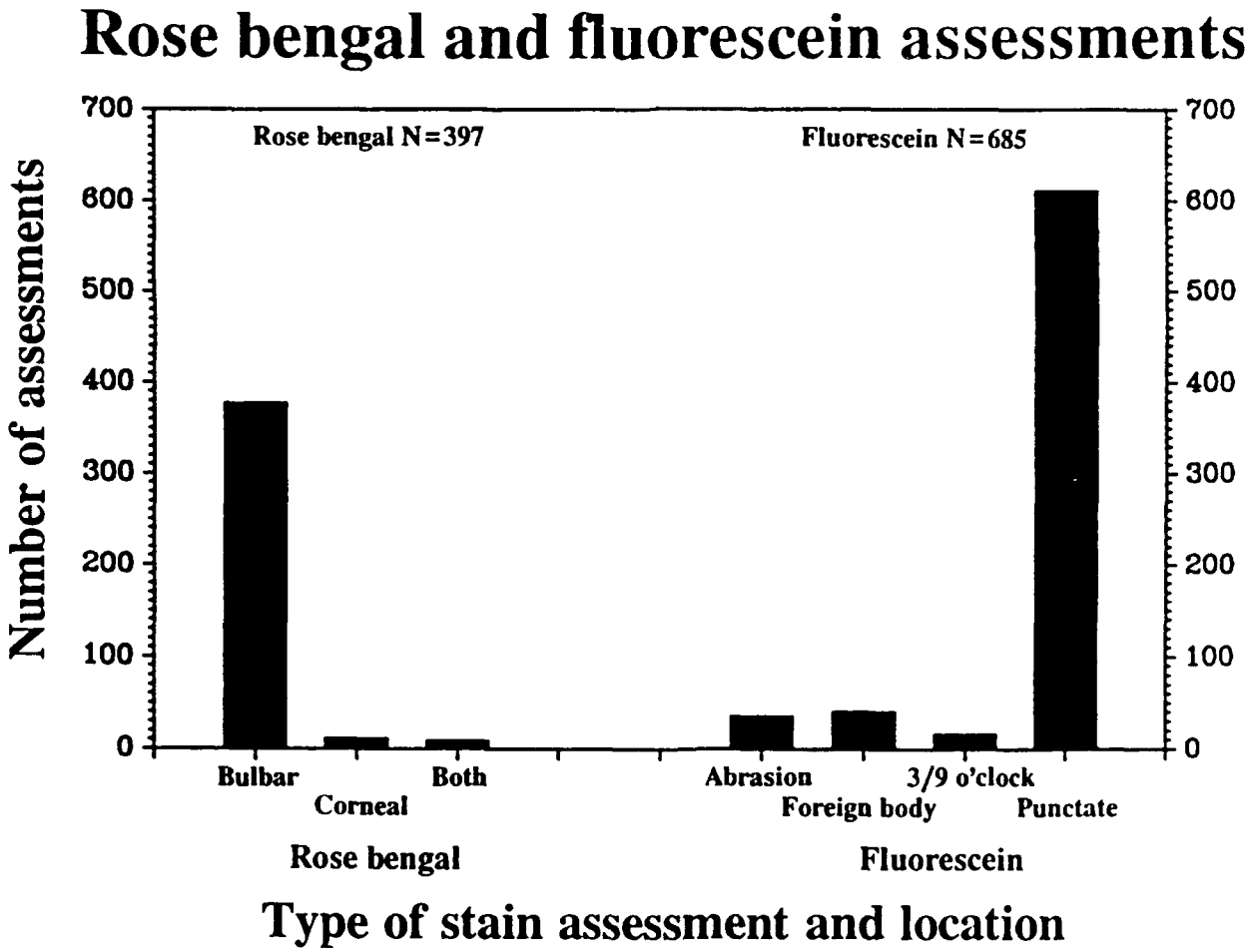


Figure 8. Rose bengal and fluorescein assessments.

devitalization increased over the first 2 days of extended wear, the fluorescein-detected barrier defects continually increased in magnitude with extended wear. This divergence suggests the presence of two separate stress-inducing processes on the anterior surface of the eye. Yet, our own subjective assessment suggested the primary cause of both types of stain uptake to be desiccation. Another section of this report demonstrates soft lens dehydration that stabilizes after 2 to 3 days wear. If lens-induced water loss from the tissue was the appropriate model for both the exhibited rose bengal and fluorescein staining processes, then they both would stabilize after 2 to 3 days of lens wear. Only the rose bengal data fits this pattern; therefore, cell devitalization is likely secondary to lens dehydration mechanics.

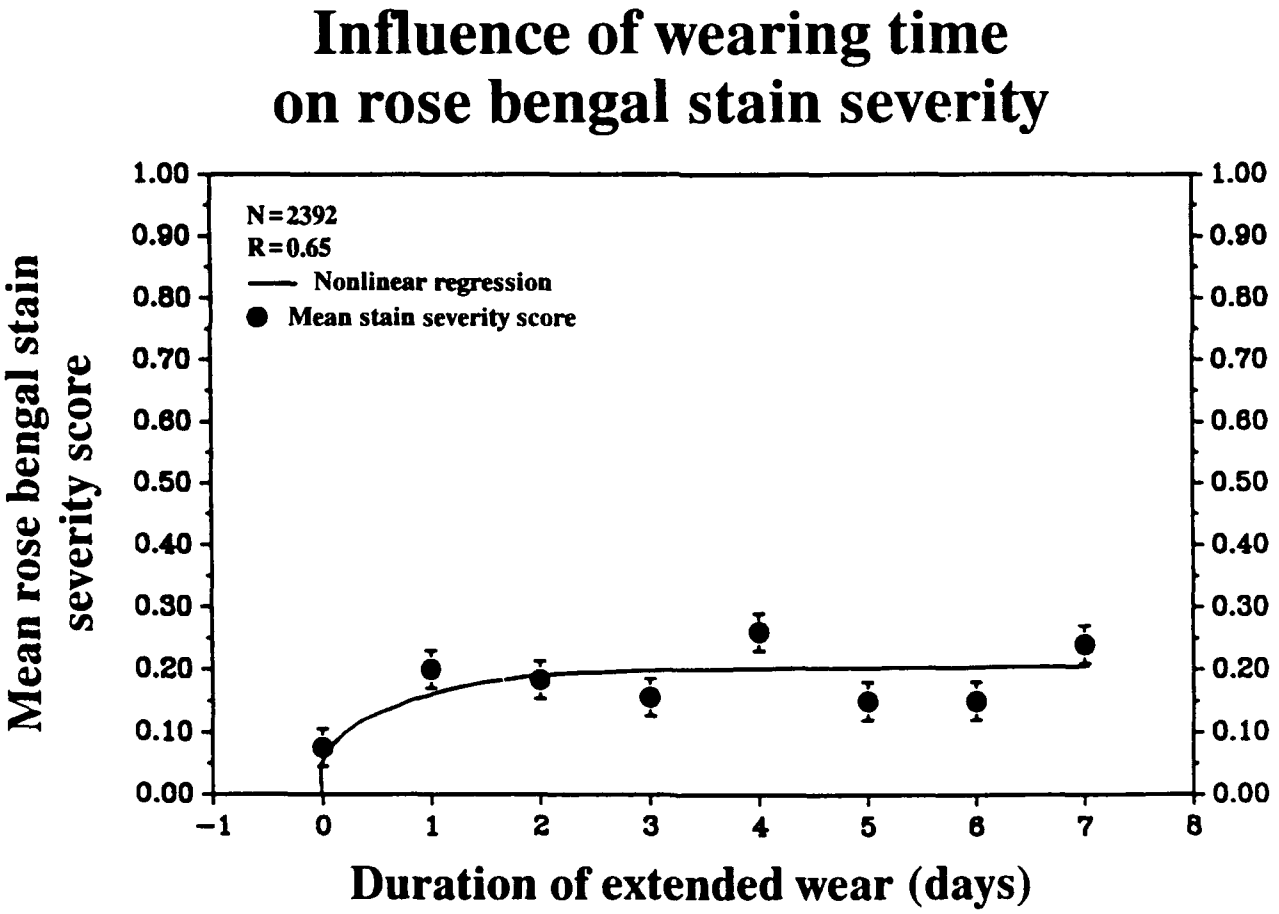


Figure 9. Influence of wearing time on rose bengal stain severity.

Clearly then, the extended soft wear-stimulated deficit in the corneal epithelium's barrier function is not secondary to a desiccation process. An alternative hypothesis involves corneal metabolic waste accumulation under the soft lens that eventually proves toxic to the various layers of the cornea. Epithelial influence is seen early via punctate fluorescein staining; endothelial influence is seen later via morphological changes. It is likely the epithelial barrier function loss is linked to bacterial invasion of the cornea in ulcerative keratitis.

Tear break up time (BUT) was assessed using, as the measure, the duration or maintenance of a smooth tear film after a deliberate blink. Timed measurements were documented with high molecular weight fluorescein while lenses were worn, and with standard fluorescein strips when lenses were removed. A correlation of BUT methods was not significant (p=0.29; Figure 12). While the two methods have been shown to clinically correlate (Patel, Farrell, and Bevan, 1989), it is obvious from

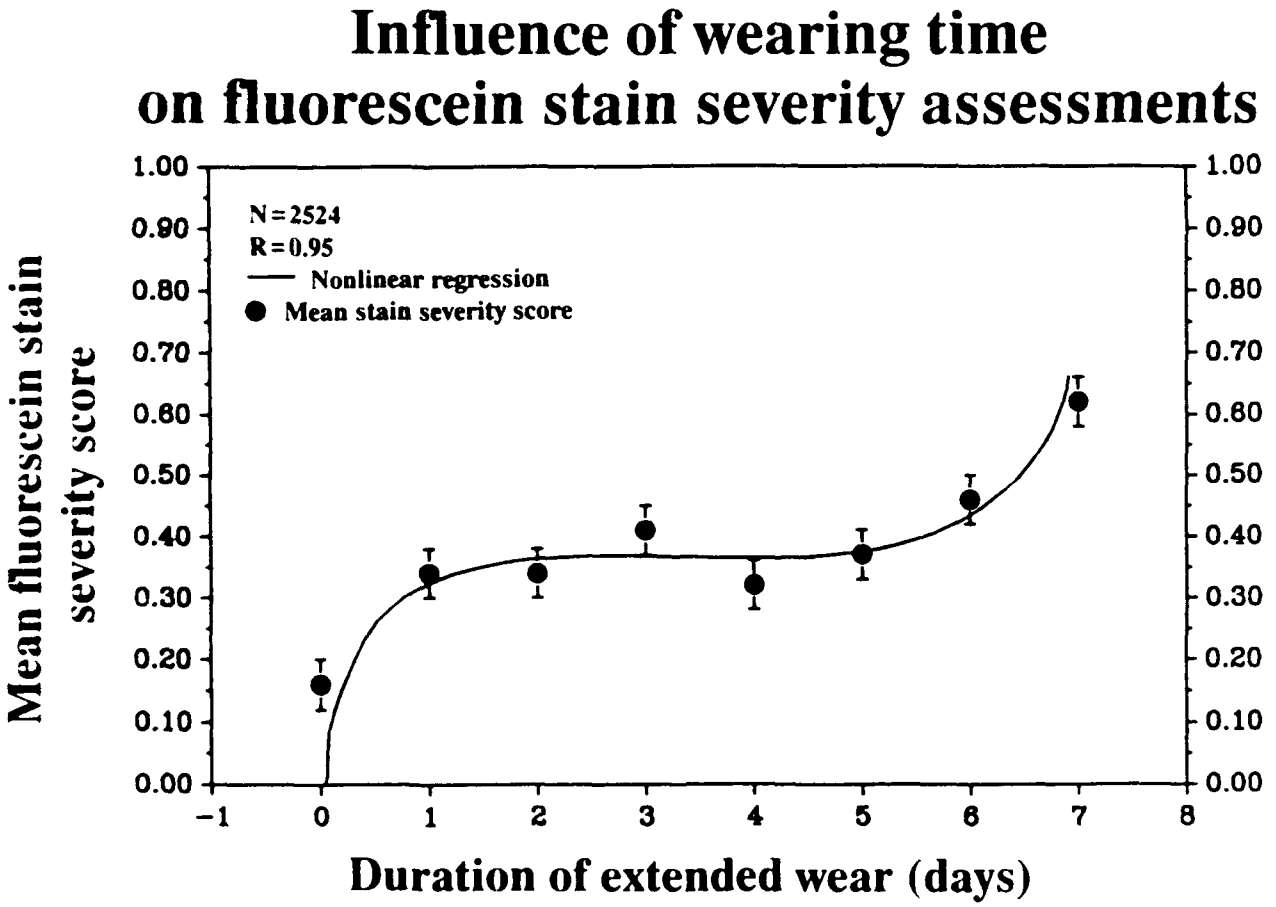


Figure 10. Influence of wearing time on fluorescein stain severity.

these data that the presence of an unstable precorneal tearfilm does not mean that a contact lens will not be covered by a stable tear film. The obverse also is true, in that a stable precorneal tearfilm does not guarantee maintenance of an optically smooth front contact lens surface. Because of this lack of mutual exclusion, both methods of tear film assessment are recommended in routine patient evaluation.

Precorneal tearfilm stability in normal individuals has been positively related to tear production as measured by the Schirmer tear test (Patel, Farrell, and Bevan, 1989). Yet, dry eye patients (keratoconjunctivitis sicca) have been shown to exhibit no relationship between tearfilm stability and tear production (Rolando, Refojo, and Kenyon, 1983). These findings conflict with a basic understanding of tearfilm behavior. Logic dictates

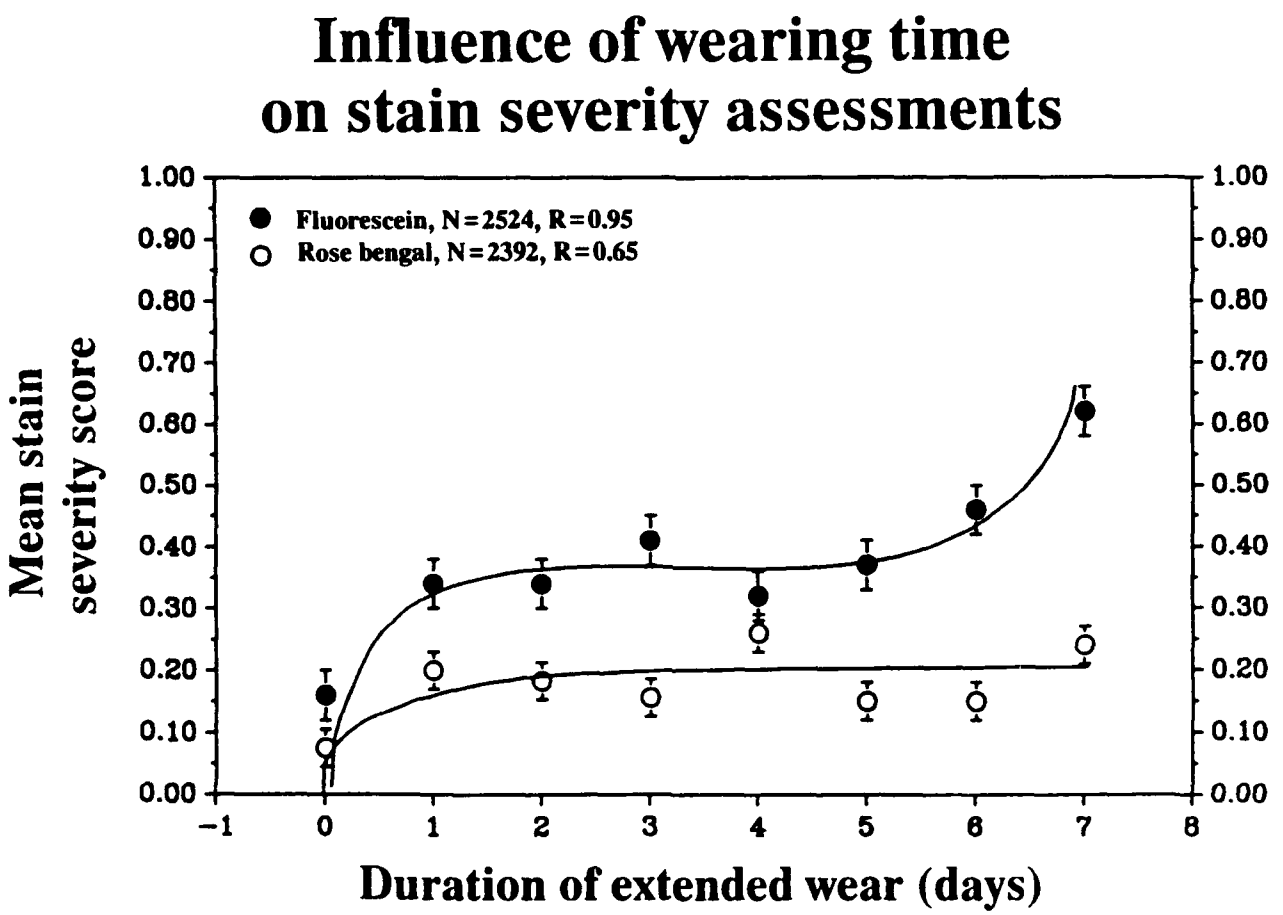


Figure 11. Influence of wearing time on stain severity assessments.

that a stable precorneal tearfilm will have little need for plentiful tear production, and an unstable tearfilm will secondarily lead to reflex tearing. Therefore, the referenced findings don't make clinical sense.

In an effort to test at least a part of these disparate findings, tear-film stability assessments and tear production measurements were correlated in the study subjects. The correlation was very poor (R=0.07) and the ANOVA was not statistically significant (p=0.12). Therefore, contrary to inferences drawn by Patel et al. (1989), the present data indicate that there is no relationship between tear BUT and tear production in clinically normal contact lens wearers. Additional assessments of BUT (both high molecular weight fluorescein and standard fluorescein strips) did not correlate well with number of days lenses had been worn prior to the followup exam. Therefore, even though protein buildup is acknowledged to occur over wearing time, it apparently does not influence this type of

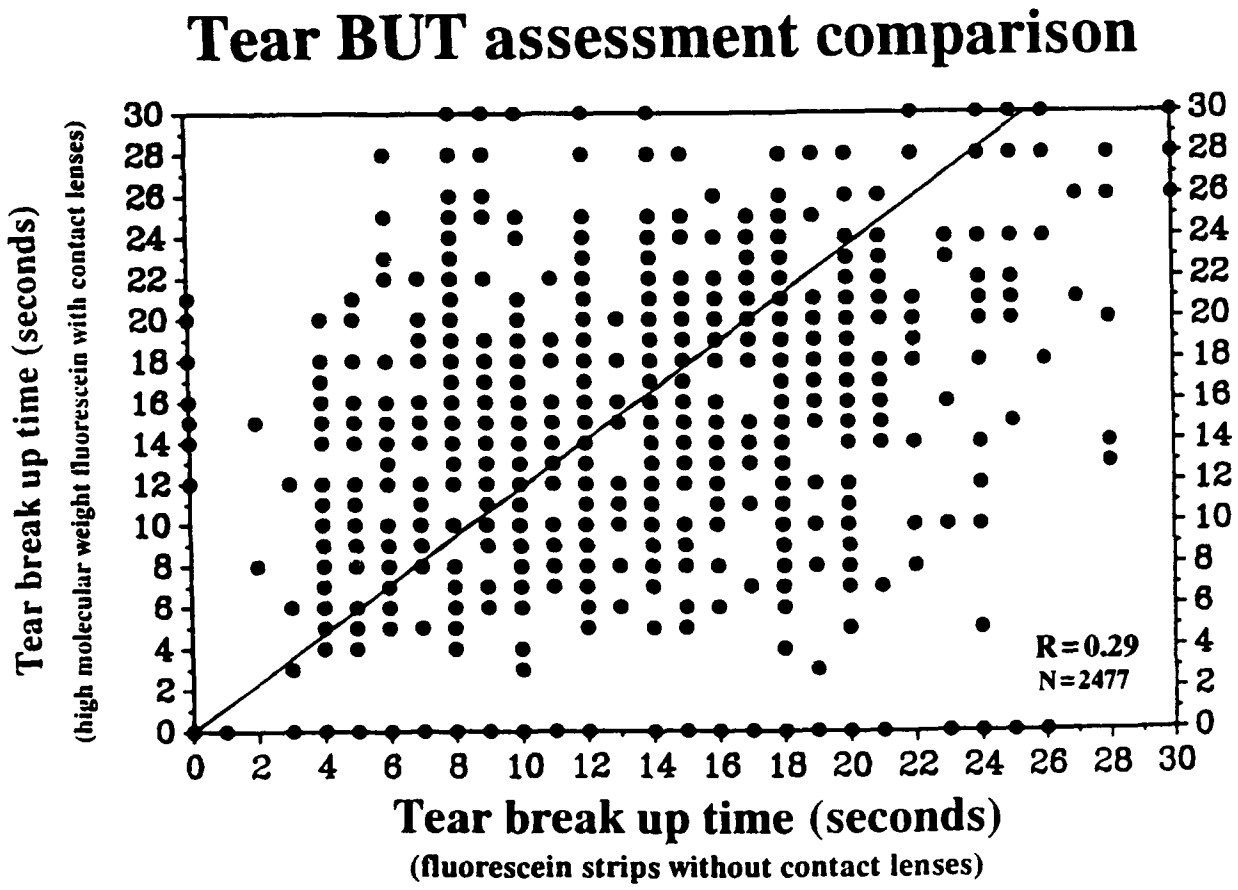


Figure 12. Tear BUT assessment comparison.

tear BUT assessment. As a result, both tear stability and production assessments should routinely be performed on the initial contact lens evaluation, but are unlikely to offer any new information on followup examination.

Practically speaking, none of the subjects had insurmountable objective or subjective problems wearing the lenses used in this study, even those with less than 5 mm of tear strip wetting. Subjects had been given an ample supply of unit-dose, sterile, unpreserved wetting solution, and were encouraged to use as much as they needed. Extra supplies of wetting solution were readily available at the subjects request, if required.

Safety concerns

Safety issues were of the primary concern at the start of the study. The main worry centered on the possibility of a contact lens-induced sudden incapacitation causing loss of aircraft control. As the initial local phase of the study unfolded, it became obvious that sudden incapacitation would not be an issue, prompting expansion of the protocol to the Armywide effort, and later the Desert Shield/Storm inclusion. Again, the initial worry proved to be unsubstantiated. Aircrew wore their soft lenses in a doors-open or -off scenario with no adverse effects on lens comfort. RGP lens wearers had a lot of trouble, however, with foreign bodies in the same flight profiles.

There were three occurrences involving contact lens-wearing subjects that prompt mention in the safety arena. 1.) There was one equipment failure in flight that resulted in a "crash" landing that was controlled with minimal damage to the aircraft and no damage to the subject. 2.) There was a mishap involving two AH-64s hovering in an LZ. The main rotor blades impacted, resulting in a crash, with moderate to severe damage to both aircraft and one case of severe burns secondary to a postcrash fire. Both frontseat aviators were contact lens subjects, but neither was at the control of their aircraft at the time of the incident. In both these episodes, Army Safety Center investigations ruled out contact lens wear as a contributing factor. 3.) The last safety-related episode involved an operationally-stimulated ejection (bad weather and low on fuel) from an intelligence fixed-wing aircraft (RV-1 Mohawk). The pilot stated that his contact lenses stayed in place during the ejection, whereas glasses would have been lost as a result of the windblast on ejection. At the start of this program, the major safety fear was that of sudden pilot incapacitation due to lens loss or foreign body sensation. These concerns were needless. Based on questionnaire responses recorded later in this report, it's entirely possible contact lens wear may be safer than flying with glasses.

Subject sentiment

Specific subjective assessments by formal questionnaire are addressed elsewhere in this document. Verbal feedback during the course of the study was always very positive. Subjects were especially appreciative of the increased apparent field-of-view while on NVG operations. They also commented on the lack of distracting reflections that can be a problem with glasses. Apache student pilots were particularly full of praise for contact lenses after finishing their 2 weeks of training "in the bag" when their only view of the outside world is via the HDU because the windscreens are completely obscured. The overall consensus supported the idea of routine contact lens use while performing flight duties.

Ocular health

General complications of contact lens wear also were tracked in order to determine possible impact on medical resources and unit readiness. The major complication associated with extended soft lens wear, ulcerative keratitis, will be discussed fully in a separate section. Overall, few ocular complications were encountered. This despite that a detailed monitoring system had been established through flight surgeon, optometry, and ophthalmology channels at the Army installations involved in the study. There were six cases of acute, ulcerative keratitis; six cases of peripheral corneal infiltrates noted on followup exams; three cases of bacterial conjunctivitis; two cases of viral conjunctivitis; two cases of anterior uveitis/iritis; and one case of a severe allergic reaction. Many of the above conditions were probably not contact lens related, although the anterior uveitis cases may have been related to a temporary tight lens condition. In order to rule out a tight lens fit, both subjects were put back in lenses of the same parameters as before; there were no recurrences of the uveitis. In the case of the severe allergic reaction, the contact lenses may have been protective in nature. After flying through a localized, dense "fog" in a doors-off condition while wearing his soft lenses, a special operations pilot experienced severe conjunctival redness and itching accompanied by external eyelid erythema. On slit lamp examination, his corneas were found to be uninvolved in the apparent allergic or hypersensitivity process.

Synopsis

In summary, results were very positive compared to initial expectations. Success rates were acceptable in light of the limited lens types and parameters used. Clinical evaluations were essentially normal with no remarkable contraindications to lens wear noted. Subjective evaluations by the contact lens wearers were highly positive. Safety of flight concerns were

essentially unfounded. Finally, the ocular health impact was minimal compared to the number of subjects, the duration of the study, and the varied and stressful environments encountered. Therefore, the basic general conclusion is that contact lens wear should be adopted as a routine means as correcting the refractive errors of Army aircrew. Specific conclusions and recommendations are outlined in another section after the detailed clinical, physical, and physiological analyses.

Detailed analyses

Corneal curvature assessment

Introduction

The purpose of this portion of the investigation was to assess possible water content-related differences in how soft contact lenses drape across the corneal surface. Related to this initial assessment was an interest in documenting possible corneal cylinder masking differences, as well. Anecdotal reports have indicated water content differences can affect physical lens behavior in situ. However, a literature review failed to provide any data on this topic.

Methods

Over a 3-year study, the 223 subjects assigned to AH-64 and special operations units were fitted with either a 38 percent or 58 percent water content soft lens of analogous base curve (8.8 mm) and diameter (14.0 mm) under disposable wearing conditions. Subjects received followup exams at 24 hours and 7 days postfitting. Quarterly followup exams were conducted thereafter. An autokeratometer was used to measure both corneal and anterior lens surface curvatures on all exams; similar corneal and contact lens surface cylinder assessments also were recorded.

Results

Grouped data plots of anterior soft lens curvature (flattest K-reading) as a function of underlying corneal curvature for each lens type indicate a collective linear relationship that does not statistically vary by water content in the two types of lenses studied (F ratio approaches 0.000 and p approaches 1.000; Figures 13 and 14). Paired corneal cylinder plots reinforce the above result by revealing no significant masking differences between the two lens types ($p = 0.201$; Figures 15 and 16).

Discussion

Based on these data, it is concluded that physical lens fit is independent of water content when the base curve and diameter are kept constant. This contradicts the notion of greater corneal cylinder masking ability of low water content soft lenses. However, it is recognized that the measurement systems used to gather these data record central corneal parameters only. Therefore, this investigation is conclusive only for lens behavior over a restricted area of the central cornea.

Using a corneal topographical modeling system and a digitizing board, a preliminary analysis of overall anterior lens surface topographic areas reveals a marginal statistical difference between the two types of soft lenses on one test subject (Figure 17; p = 0.048). However, the isolated central

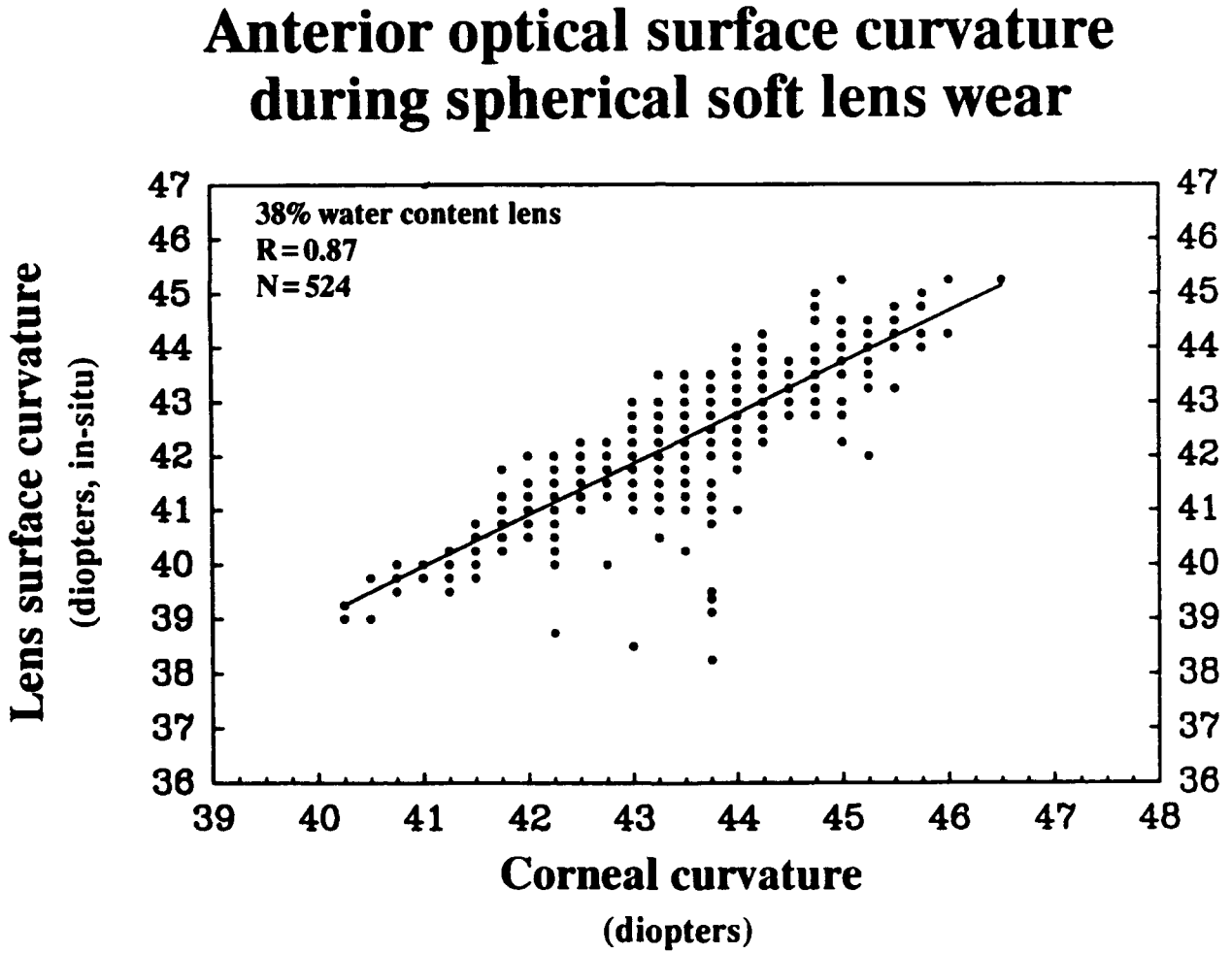


Figure 13. Anterior optical surface curvature during spherical soft lens wear (38 percent water content lenses).

corneal topographic measurements by this method were not significantly different ($p = 0.32$), reinforcing the autokeratometer results. Further data are required before any conclusions can be made regarding universal topographic differences between lens types and the possible significance of such data.

Corneal aesthesiometer assessment

Introduction

The routine wear of old-technology PMMA contact lenses has been implicated in a progressive loss of corneal sensitivity (Farris, Kubota, and Mishima, 1971). This loss of sensory nerve

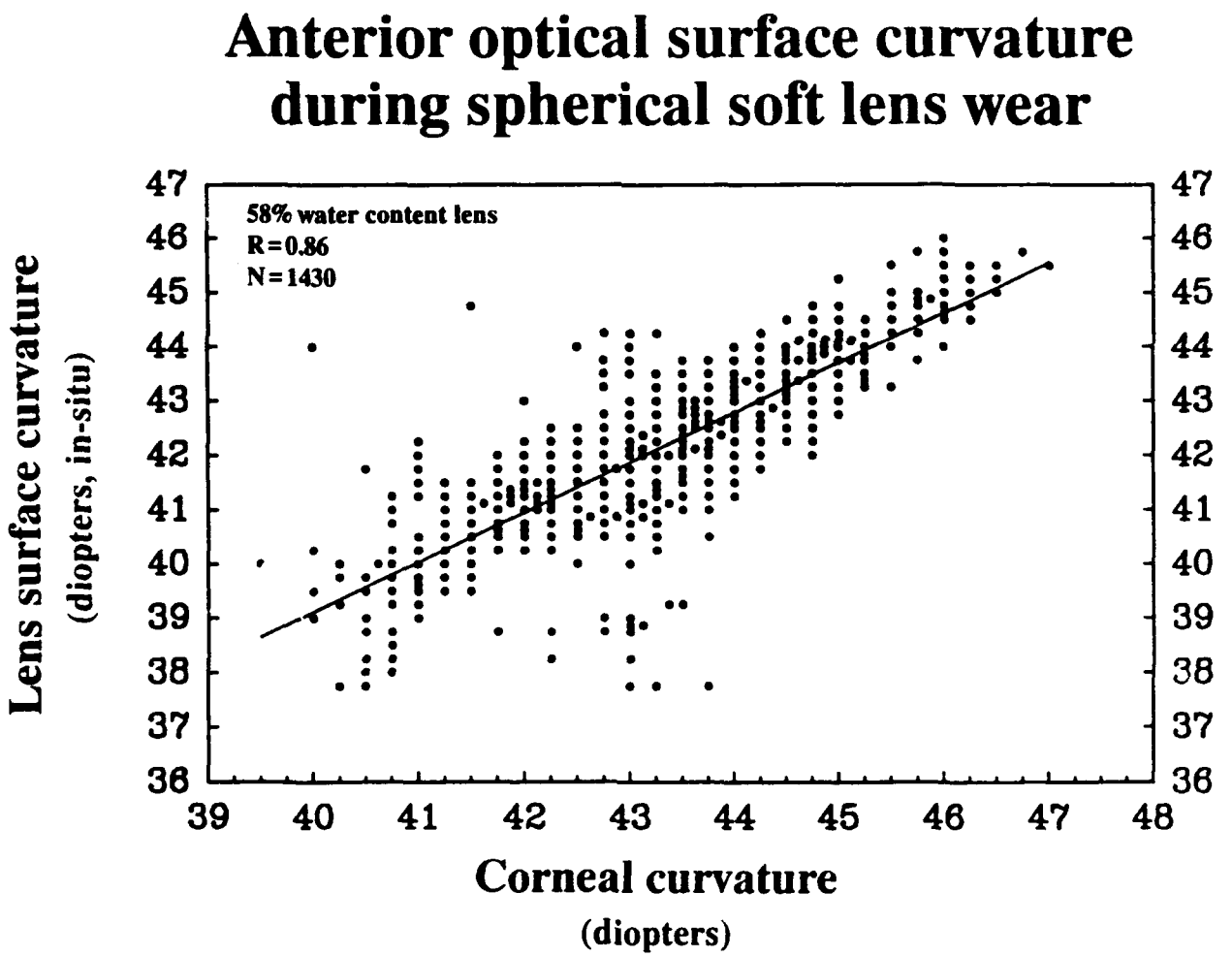


Figure 14. Anterior optical surface curvature during spherical soft lens wear (58 percent water content lenses).

function was attributed to chronic hypoxia associated with contact lens wear. New-technology soft lenses and RGP lenses have not appeared to induce this clinical complication, although there are no literature citations to support this notion. An aesthesiometer was used on each examination (initial and all followups), in order to verify the maintenance of normal corneal sensitivity.

Methods

The Cochet and Bonnet* aesthesiometer consists of a nylon monofilament fiber held within a sliding tube. Initially, the fiber is fully extended to a scale reading of 6. The outer 1 mm tip is disinfected by wiping with an alcohol preppad. After air drying, the tip of the fiber is then touched perpendicularly to the apex of the subject's cornea. Enough pressure is applied to

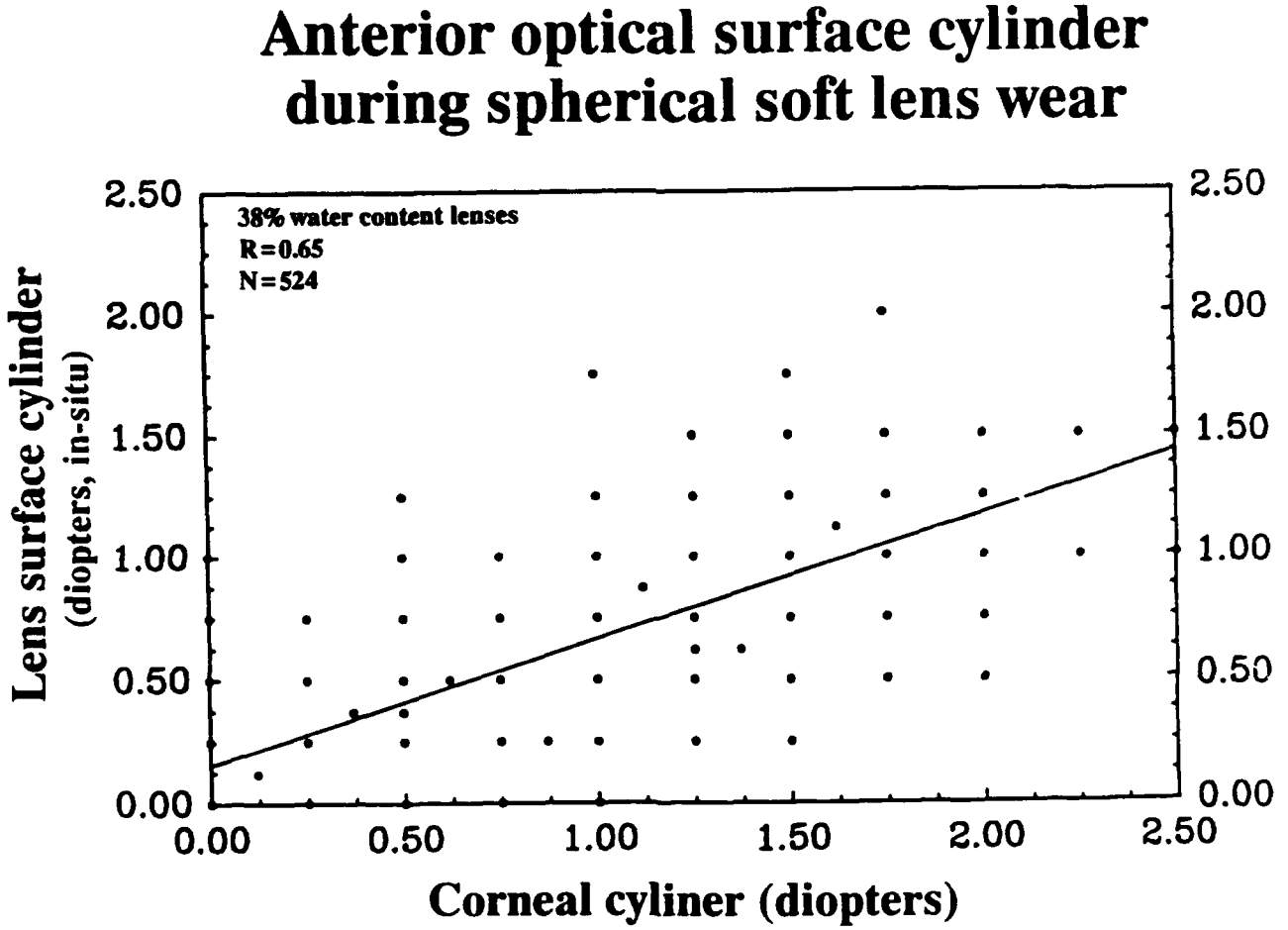


Figure 15. Anterior optical surface cylinder during spherical soft lens wear (38 percent water content lenses).

obtain a 4 percent deflection of the fiber (first visible bending). If the subject does not feel or react to the fiber's presence, the fiber is withdrawn, shortened to the next setting demarcation (5.5), and reapplied. This series is repeated until the subject senses or reacts to the fiber. The fiber settings can be translated into pressure values in grams per square millimeter, by way of a calibration plot provided by the manufacturer (Figure 18).

Results and discussion

Corneal sensitivity measurements were not statistically significant as a function of time in the protocol ($p=0.37$), as a function of number of days of lens wear ($p=0.42$), or as a function of type of contact lens ($p=0.18$). Corneal sensation thresholds ranged between approximately 1.3 and 1.5 grams/mm^2 (Figure 19). Although overall lens type classification was not a

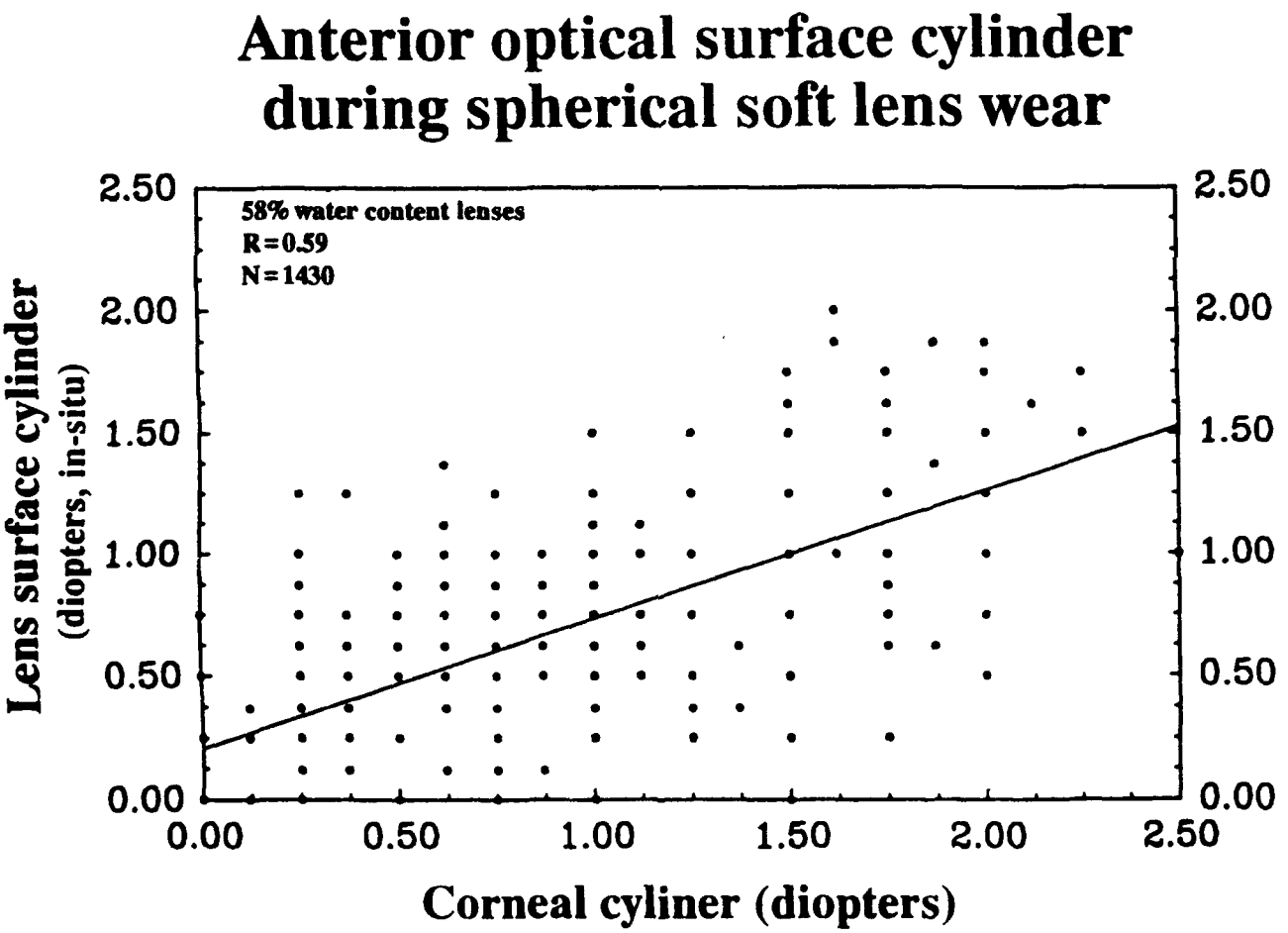


Figure 16. Anterior optical surface cylinder during spherical soft lens wear (58 percent water content lenses).

significant factor affecting corneal sensitivity, RGP lens wearers did exhibit statistically higher corneal sensation thresholds than 38 percent water content soft lens wearers ($p=0.04$). Mathematically, the RGP lenses transmit greater amounts of oxygen than the 38 percent water soft lenses. Yet,

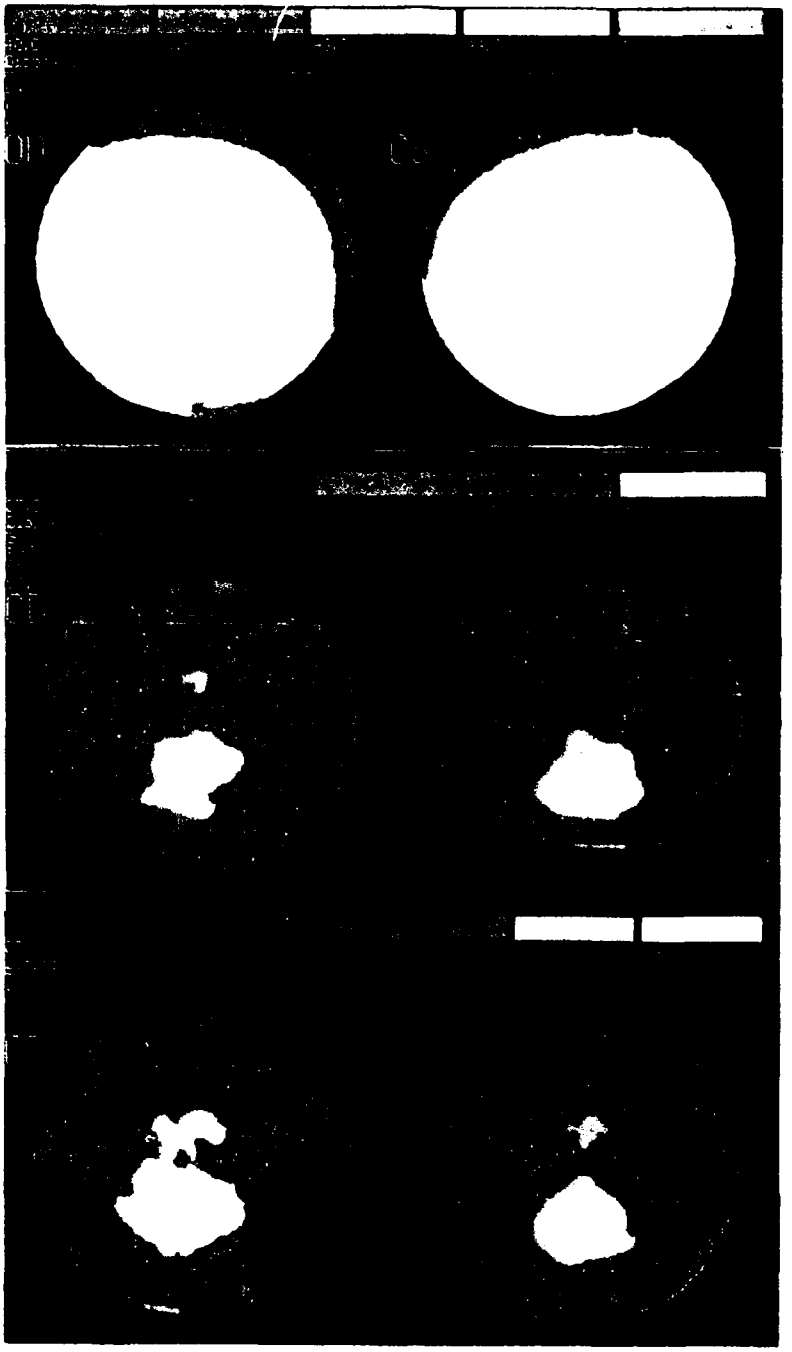


Figure 17. Corneal and anterior lens surface topographies.

paradoxically, the RGP lenses seem to raise the corneal sensation threshold (i.e., RGP wearers' corneas are less sensitive). Therefore, oxygen availability is not the sole determinant of potential corneal sensitivity changes. A likely contributor to the elevated threshold in RGP wearers is the adaptation mechanism that permits subjects to become physically comfortable in the presence of a rigid lens. The differences noted, while statistically significant, are not clinically significant and therefore merely of strictly theoretical interest.

Conclusion

The lenses used within this protocol, and presumably contact lenses of similar physical structure and oxygen transmitability, did not have an adverse effect on corneal sensitivity. Therefore, it can be concluded from this limited perspective, that these lenses are safe for long term use by Army aircrew.

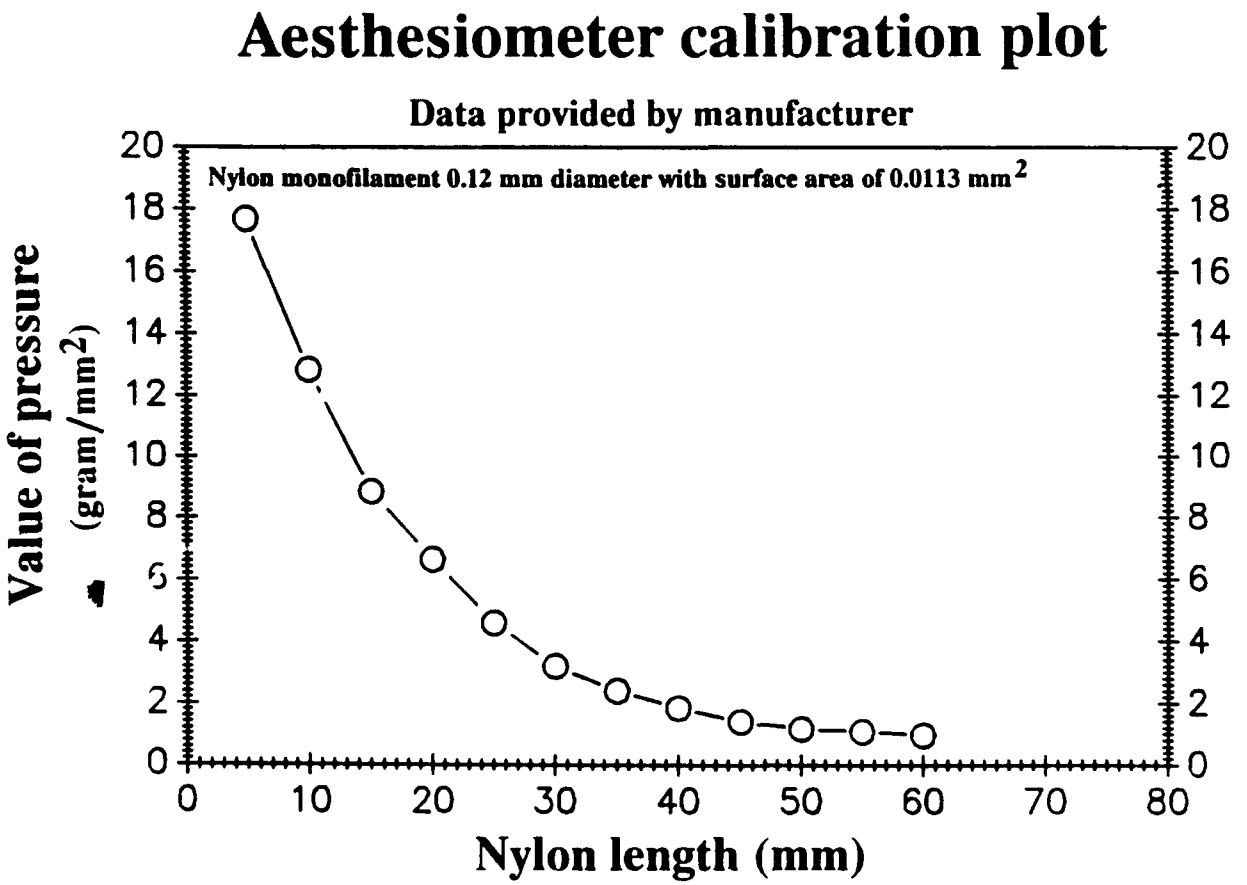


Figure 18. Aesthesiometer calibration plot.

Sterile peripheral infiltrates

Background

Peripheral corneal inflammatory diseases have been thought to be associated with immune complex formation (Mondino, 1988). The inflammation-stimulating antigen may be exogenous, as in Staph. aureus exotoxin induced infiltrates. The antigen also may be endogenous, as in Mooren's ulcer. Either mechanism of action could contribute to contact lens related peripheral ulcer formation (Fisch, 1990). Although not a severe complication of extended wear, it is a significant clinical finding, possibly requiring a change in contact lens materials or parameters.

As reported in the descriptive section of the results, there were six cases of sterile, peripheral infiltrates or ulcers. The onset, by history, was characterized by a mildly red, irritated eye with complaints centering on a foreign body sensation. The subjects discontinued lens wear, as instructed. However, they

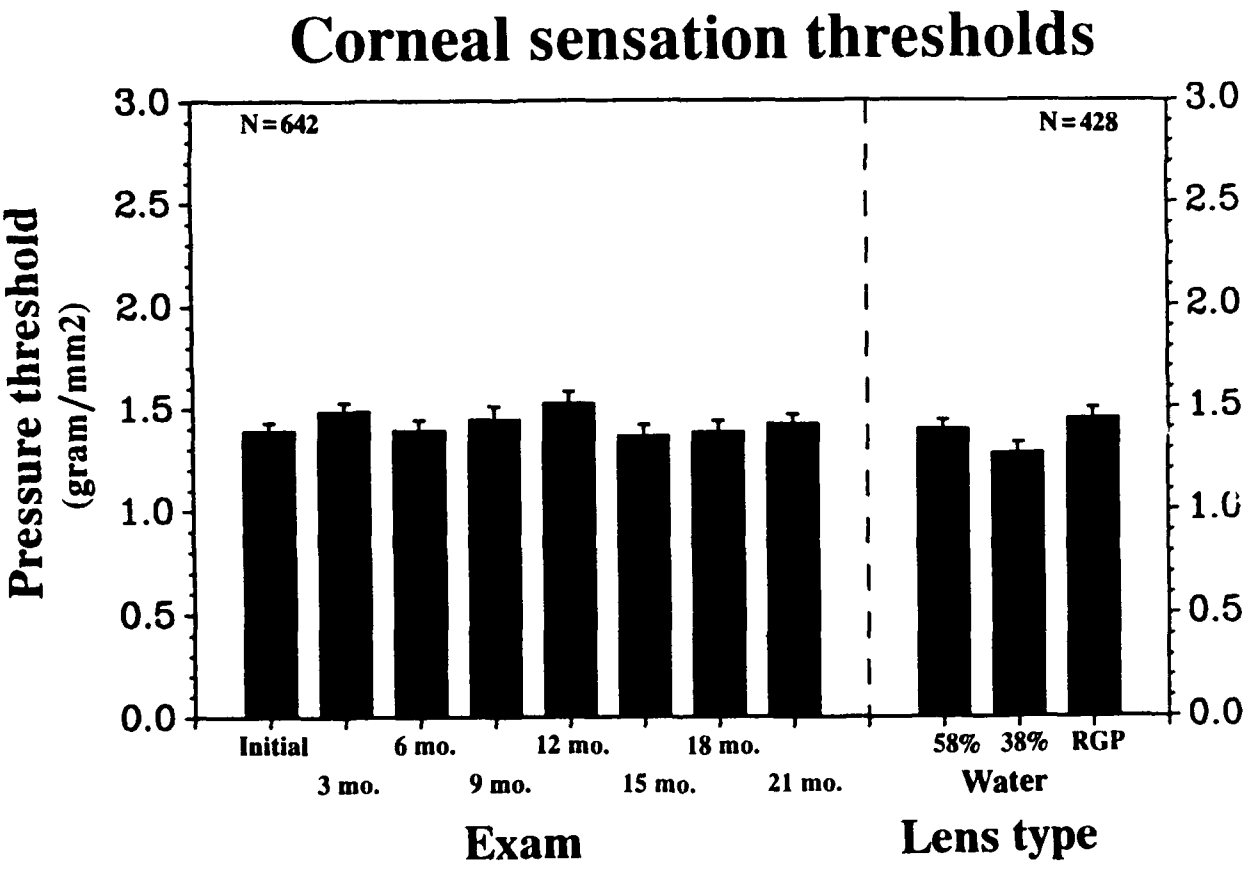


Figure 19. Corneal sensation thresholds.

did not seek objective evaluation also as instructed, since symptoms abated on lens removal and disappeared entirely within 24 to 72 hours. At the time of symptom abatement, normal lens wear was reinstituted by all affected subjects. On the required quarterly followup exam, the existence of a residual scar was observed, and the supporting history obtained.

Objectively, there was indication of a localized infiltrate concentration at the level of the anterior stroma near the limbus; location in all cases was restricted to the inferior hemisphere of the limbus (between 3 and 9 o'clock). While the general shape of the lesions could be described as circular, many were slightly oblong with the central axis appearing to parallel the limbus (Figure 20). Subsequent follow up examinations documented a gradual resolution or elimination of the precipitated immune complexes.

Figure 20. Peripheral, sterile ulcer.

Discussion

The location and appearance of the peripheral corneal lesions noted above are reminiscent of another phenomenon associated with soft contact lens wear: subcontact lens bubble formation at altitude (Flynn et al., 1987). Described soft lens bubbles occurred in 24 percent of the study eyes (22/92), and were always formed at the limbus. None were ever detected over the central cornea. Once formed, these peripheral bubbles increased in size and coalesced with increasing altitude. The bubbles did not disappear with blinking, but once descent was initiated, the dissipation process only took several minutes. The authors suggested that observed bubbles were the result of an induced expansion of previously existing bubble nuclei trapped by the soft contact lens acting as a semipermeable membrane.

While bubble composition was never identified, the mechanism of bubble nuclei formation was suggested to be via the negative hydrostatic pressure "produced from the contact lens tear pump." An analysis of research in the areas of tear film pH and associated s ft contact lens wear underscores an alternative explanation indicating a major subcontact lens bubble nuclei source to be corneal-vented carbon dioxide. If this hypothesis is correct, then CO_2 bubbles, as a metabolic byproduct, could be used to model subcontact lens metabolite trapping. The pattern of epithelial punctate staining described earlier in this report could conceivably be a direct result of isolated or uncoalesced carbon dioxide bubble-nuclei trapping across the surface of the cornea.

A gross comparison of the six sterile peripheral infiltrates to published soft lens bubbles highlights a correlation in both limbal position and relative shape. This relationship could describe the underlying process of sterile peripheral infiltrate formation as a localized inflammatory or hypersensitivity response to peripherally coalesced and concentrated endogenous metabolic byproducts trapped under the soft lens. The proposed CO_2 bubble formation model then could directly be applied to the assessment of pertinent soft contact lens fitting parameters (i.e., base curve, diameter, and corneal curvatures) governing a tight vs. an appropriate fit. Such a model would be extremely useful in providing a quantitative nomogram for soft contact lens fitting in lieu of the subjectively qualitative methods in current use.

Bacterial ulcers

Background

The primary drawback to the routine use of contact lenses by Army aircrew is the risk of bacterial ulcerative keratitis. This serious ocular complication has been closely linked to the use of extended wear soft lenses (Galentine et al., 1984; Weissman et al., 1984; Chalupa et al., 1987). Alternatively, poor lens hygiene compliance has been suggested to be the primary cause of daily wear soft lens-induced corneal infection (Mondino et al., 1986). Since field conditions for Army aircrew would place a major hygiene challenge upon contact lens wearers, it was decided to use a disposable, extended wear soft lens system. It was hoped the decreased risk of hygiene and compliance problems by going disposable would offset the increased risk posed by extended wear.

There were a total of six cases of bacterial ulcerative keratitis. Although corneal scrapings and cultures were negative, all cases were presumed to be bacterial based on:

physical location and appearance of the lesion, severity of associated signs and symptoms, and effectiveness of antibacterial therapy. All cases were initially seen by general medical practitioners and treated with topical antibiotics prior to specialty referral, so it isn't surprising that scrapings and cultures were negative. All subjects recovered from the acute phase of the infection within 4 to 8 days, primarily as a result of the subject promptly seeking medical attention. All recovered visual acuity of 20/20 or better within the noted time. An example ulcer is shown in Figure 21 (Lattimore and Varr, 1991). While affected aircrew were temporarily grounded during the course of the infection, all were eventually returned to full flight duty, and all voluntarily returned to contact lens wear, as well. To date, there have been no recurrences of ulceration in affected subjects. Since fungal dermatitis was a major problem for troops deployed to Southwest Asia, there also was concern for possible fungal keratitis in the deployed portion of our study group. However, no cases were documented.

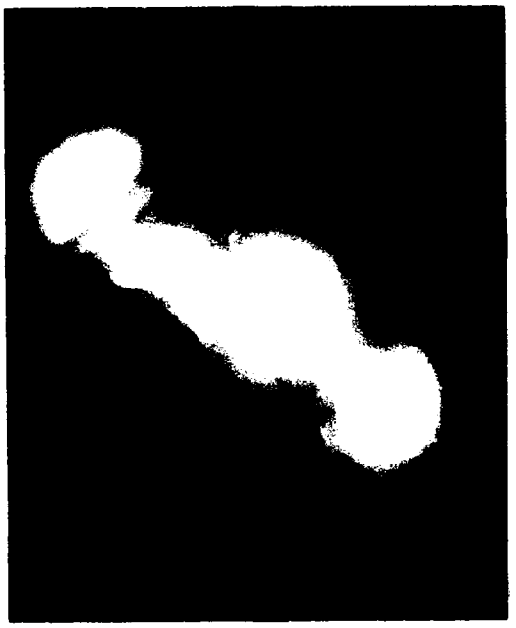


Figure 21. Paracentral, bacterial ulcer.

Discussion

The combined ulcerative keratitis risk of all study subjects (all original AH-64 protocol subjects plus Desert Shield/Storm subjects) from November 1988 through September 1991, equated to 1/112/year, or 8.93/1000/year. This combined risk falls within the wide range of risk estimates (2.1/1000/year by Poggio et al., 1989; 4-6/1000/year by Schein et al., 1989; 15/1000/year by Grant, Kotow, and Holden, 1987; 48/1000/year by Efron et al.,

1991) proposed for nonaphakic extended soft lens wear in the civilian literature. The less than 1 percent level of risk for ulcerative keratitis has been judged to be acceptable within the context of other risks faced by Army aircrew members in the performance of their flight duties. However, the public health issue of placing healthy eyes at increased risk of severe infection should not be ignored. Ways of minimizing this complication should still aggressively be pursued. Possible options to be considered include planned replacement, flexible wear of soft lenses or even a daily disposable system under adverse conditions.

Hydrogel translens oxygen flux

Introduction

Many studies have examined oxygen transmittance and oxygen availability issues related to hydrogel contact lens wear. One methodology is to place a test lens on the eye, and after a specified period of wear the lens is removed. Immediately after lens removal, the oxygen uptake rate of the cornea is obtained. This postlens rate is compared to an uptake rate obtained prior to application of the test lens. Since the contact lens inhibited oxygen flow while it was in place, the newly lens-free cornea typically exhibits an increase in the oxygen uptake rate compared to the prelens baseline. This increase can be mathematically converted into an equivalent oxygen percentage (EOP) that had been available to the cornea under the lens.

Another methodology uses corneal thickness as an index for oxygen availability. Induced hypoxia can be achieved by various hydrogel lenses or by goggles that have a complete or partial nitrogen atmosphere retained between the eye and the goggle. Various levels of decreased oxygen availability will induce secondary corneal swelling. By scaling the swelling response to available oxygen levels, the investigators estimate the minimal level of oxygen necessary for normal corneal function. However, as discussed in the review portion of the report, the results are as varied as the methodologies.

Despite the wealth of oxygen data, there are no data for modeling behavior of the cornea under the hydrogel lens while it is *in situ*. Corneal behavior after lens removal simply examines the poststress response, not the concurrent stress response. Using corneal thickness as an index for the hypoxic stress-response is not a completely appropriate because other factors (bicarbonate ion, Na-K ATPase, tissue pH) have been shown to affect corneal thickness concurrent with, and independent of hydrogel lens wear (Zagrod and Connor, 1988).

Methods

The micropolarographic oxygen probe consisted of a platinum cathode (25 μm diameter) and a silver anode embedded in a plastic carrier. A potassium chloride (KCl) solution served as an electrolytic bridge between the cathode and the anode. An oxygen permeable polyethylene membrane, 25 μm thick, effectively sealed the entire electrode-KCl assembly into one operating unit. The micropolarographic system was similar to that used by Benjamin and Hill, 1986.

The experimental procedure involved applying the probe to the anterior surface of the corneal epithelium of the subject's hydrogel lens covered cornea. The sensor, when applied to the anterior surface of the in situ contact lens, provided a limited reservoir of oxygen for the underlying tissue. The average rate of oxygen depletion from the sensor reservoir, between recordings of 140 mm Hg and 40 mm Hg, became the measure of the corneal oxygen uptake rate. This, in turn, represents only a relative measure of the aerobic requirement of the cornea, since the extent that the epithelium, stroma, and endothelium each contribute to the corneal oxygen uptake rate has not adequately been established. Published estimates for the epithelium range from 55 percent to 70 percent, with an unpublished estimate ranging as high as 93 percent.

The oxygen uptake rate recordings were obtained within 5 minutes after lens application on the initial exam. Subsequent translens oxygen flux recordings were obtained at each followup examination. Data reported here were from 212 hydrogel lens wearing subjects.

Results and discussion

Translens oxygen flux as a function of number of days extended lens wear is represented in Figure 22. Although an analysis of variance of the data was not statistically significant ($p=0.25$), there is a clear pattern visible in clinical terms. The ability for oxygen to flow through a lens is shown to increase with wearing time over the first 3 or 4 days of extended wear, followed by a flux falloff after 5,6, and 7 days of wear. This non-monotonic curve is counter to the notion that a contact lens' oxygen transmittance is a fixed figure. Intuitively, a linear relationship was expected.

Obviously the ability of oxygen to flow through a hydrogel lens varies as the precorneal environment in which it finds itself varies. An undeniable component of this day 1 through day 4 flux increase, compared to the initial exam base, would be increased tissue respiratory demand. However, other factors such

as tearfilm and hydrogel fluid pH, level of lens hydration, and lens temperature can all be interrelated in governing oxygen flux.

The falloff in translens oxygen flux at day 5 and beyond may be an indicator of mucus and protein deposition. As the hydrogel surface becomes microscopically coated, the ability for oxygen to flow across the membrane may be affected adversely. If this is so, then extended wear beyond 4 days may be contraindicated. A breakdown of the data by type of hydrogel lens worn (Figure 23) shows that the process is similar for both types of hydrogel lenses used. However, it should be pointed out that paradoxically, the lower water content lens possessed a greater flux ability after 5 days of wear. Since the lenses used come from two different FDA categories, the flux differences may highlight protein deposition differences of ionic materials vs. nonionic materials.

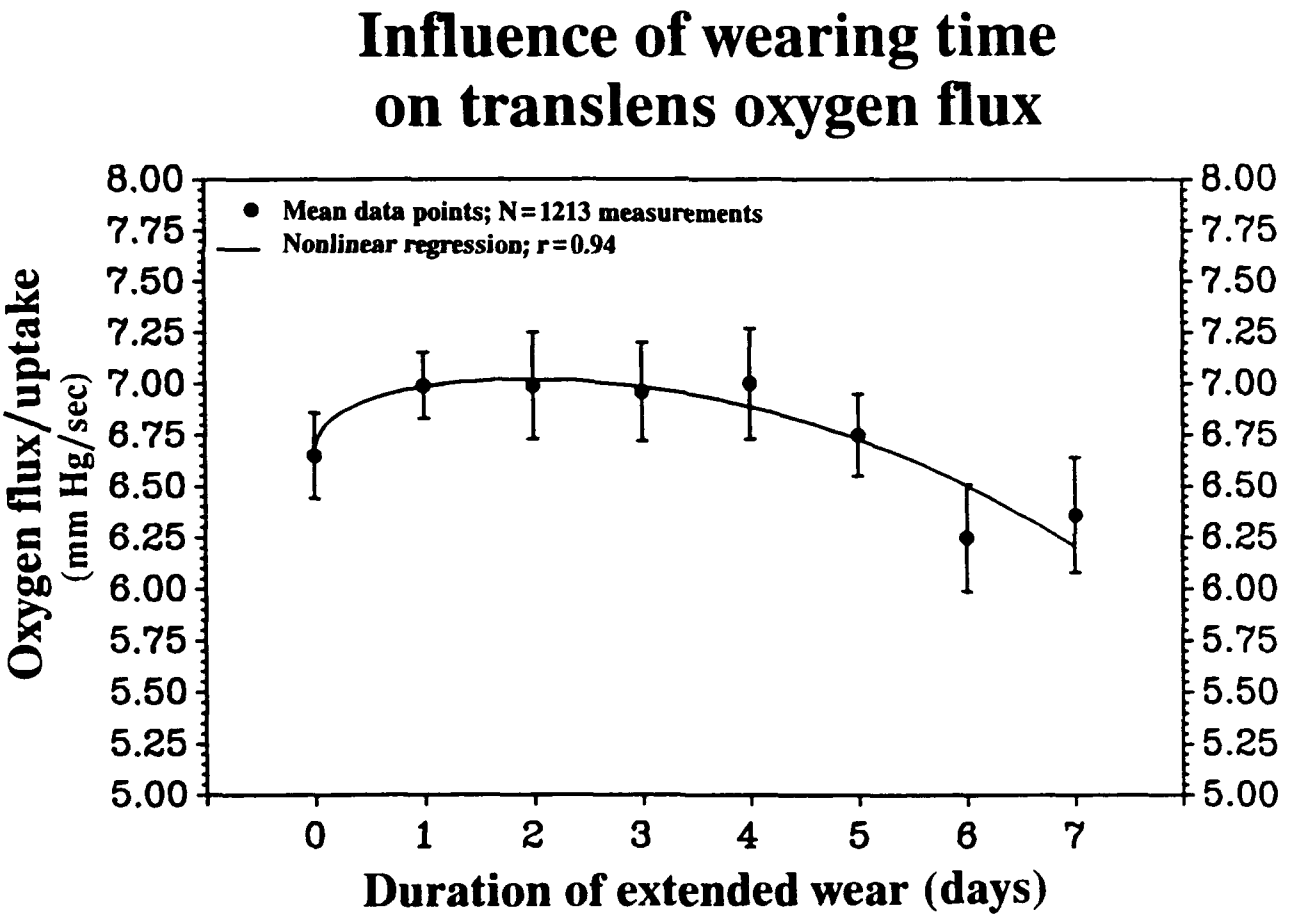


Figure 22. Influence of wearing time on translens oxygen flux (grouped data).

Conclusions

The ability of oxygen to cross the in situ hydrogel membrane is not a simplistic linear function with a fixed oxygen transmittance ceiling. Decreased oxygen flux after 4+ days of wear suggests a practical 4-day limit on the extended wear of hydrogel lenses, particularly for ionic lens polymers.

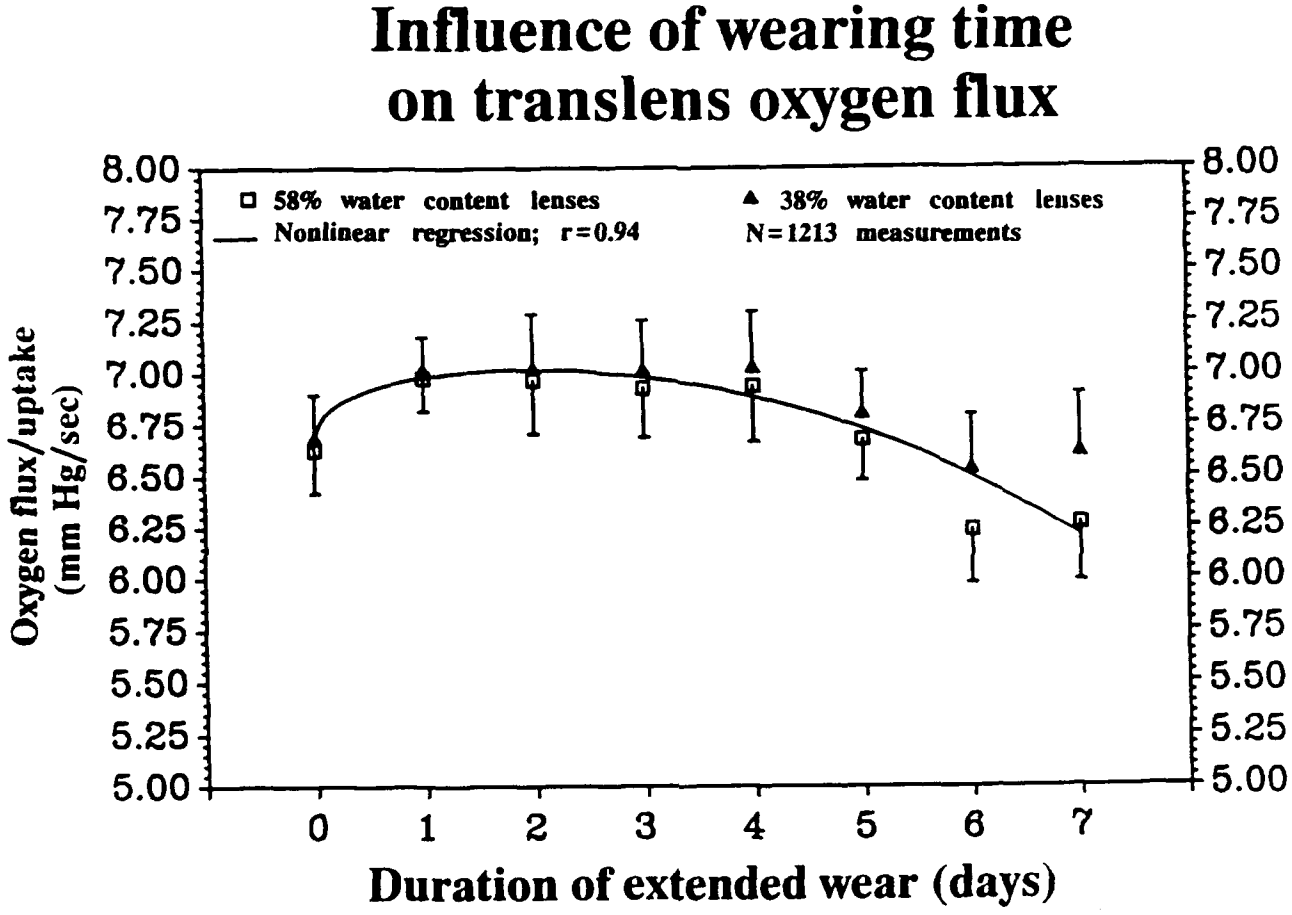


Figure 23. Influence of wearing time on translens oxygen flux (by lens type).

Anterior lens surface pH

Introduction

The anterior corneal surface is associated closely with an overlying canopy of moisture known as the precorneal tearfilm. Traditionally, clinicians have been concerned with how certain characteristics of the tears can influence corneal integrity; tearfilm formation problems and tear osmolarity issues represent

two examples of purported tearfilm influence upon the cornea. However, the tearfilm can be susceptible to influence by the cornea, as evidenced by the presence of both glycolytic and tricarboxylic acid cycle enzymes within the tear layer. The source of these enzymes has been shown not to be the lacrimal gland, but rather the underlying corneal tissue. Therefore, tear chemistry is affected directly by the cornea. Consequently, clinicians should be reminded that although anatomically distinct, the cornea and its tear film are functionally interactive.

Attempts at quantifying the normal tear pH value have yielded varying results. Although one cause of variation appears to be due to instrumentation differences, the primary cause of variation appears to be the location or source of the tear sample. Efforts at documenting the pH of the precorneal tearfilm (i.e., that canopy of mucin, aqueous, and oil directly anterior to the cornea) have obtained a mean value range of 7.45 to 7.83. Since measurements of precorneal tearfilm pH under the extended open-eye condition have been shown to match that predicted by CO_2 equilibration calculations, it is likely these values are very close to the true precorneal tearfilm pH.

Initial hydrogel lens research indicated that these contact lenses may provide a barrier to carbon dioxide (CO_2) efflux from the cornea, although at the time this was considered to be insignificant in terms of corneal physiology. However, recent measurements of tear CO_2 accumulation under hydrogel lenses, paired with the detection of a decrease in both subcontact lens and stromal pH following contact lens wear, indicates yet another functional link between the precorneal tearfilm and corneal physiology.

Materials and methods

A self-referenced pH electrode, designed for pH recording from semisolid materials was used to assess the <u>in situ</u> anterior contact lens surface pH response to continuous wear of 38 percent and 58 percent water content hydrogel lenses worn on a disposable basis. The recorded pH reading was the peak value of a transient response. Upon initial probe application, the measured pH value was within 0.2 of the final or peak value. However, a gradual drift in the alkaline direction led to stabilization of the reading, presumably due to temperature changes at the probe surface. If the probe was kept in contact with the lens beyond the stabilization period, a gradual shift in the acidic direction was noted. This has been attributed to CO_2 accumulation under the probe (Fatt, personal communication).

Subjects were on a 1-week wearing cycle, after which time the lenses were removed, disposed of, and replaced after at least one night of lens-free sleep. Use of this pH electrode method-

ology assumes the anterior contact lens surface pH measurement accurately represents both the prelens tearfilm pH and the pH of the anterior water component of the hydrogel contact lens. However, it is possible these two entities could have slightly different pH values. The pH electrode was calibrated with a 7.00 and a 10.00 pH standard solution at 35° C and disinfected by alcohol swab and surface drying between each assessment. Measurements were recorded from the contact lens in its storage packet immediately after opening, then 5 minutes after initial lens application onto the volunteer subject's eye, 24 hours after initial lens application, 7 days after initial lens application, and on subsequent quarterly followup examination. Each measurement for any one individual was taken at the same time of day in order to minimize error from individual diurnal variations. However, pH assessments across individuals occurred at varying times of day, thereby eliminating any group diurnal effect.

Results

Figure 24 provides a graphical representation of the grouped data for all lenses; lens differences were not statistically

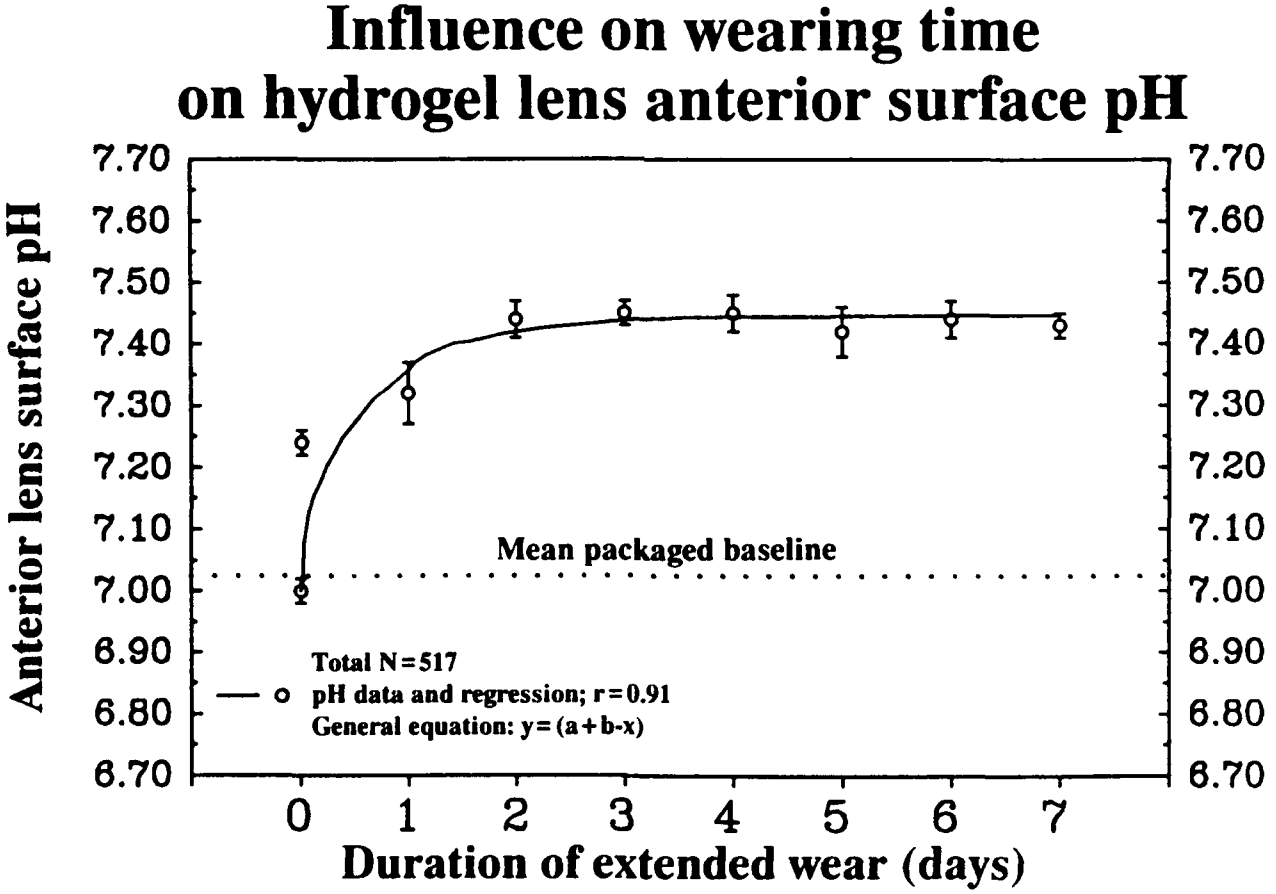


Figure 24. Influence of wearing time on hydrogel lens anterior surface pH (grouped data).

significant (p=0.43; Figure 25). The contact lenses in solution were at or very near a neutral pH of 7.00 (38 percent lenses = 7.05; 58 percent lenses = 7.00). Within the first 5 minutes of contact lens wear, the pH reading started to rise into the alkaline region (7.23); this increase in pH continued over the course of the first 2 days of wear to asymptote near the established norm (7.45). Statistical analysis (ANOVA) of pH by duration of extended wear of currently worn lenses was significant (p<0.001).

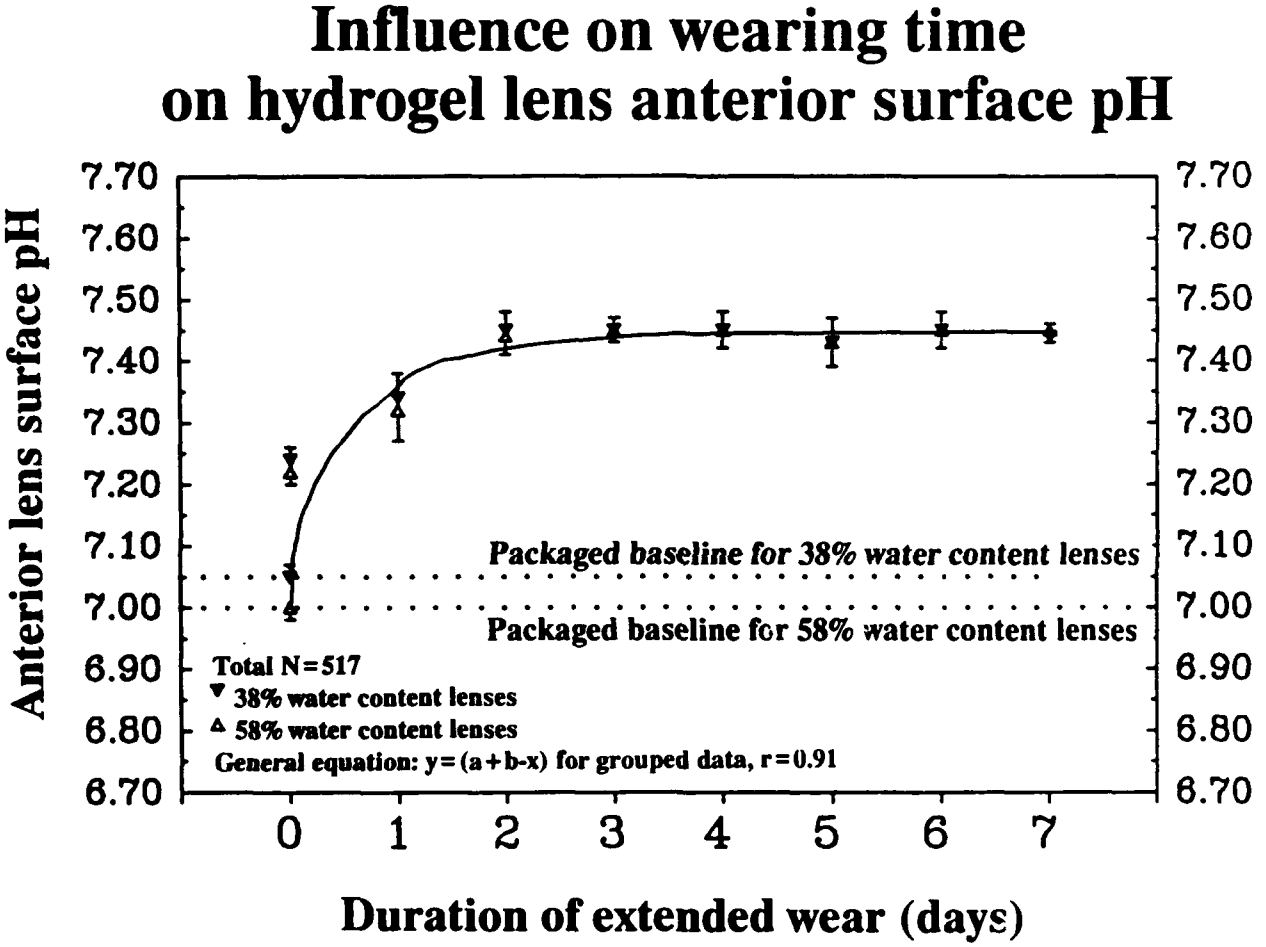


Figure 25. Influence of wearing time on hydrogel lens anterior surface pH (by lens type).

Discussion

The initial <u>in situ</u> pH reading of 7.23, taken just 5 minutes after lens application, suggests that a fluid exchange between the anterior tearfilm and the contact lens occurs very quickly. Indeed, by the point of 2 days wear the pH has stabilized near the norm of 7.45, and is not much different from the accepted published norms for the precorneal tearfilm. The initial data (days 0 and 1) are less alkaline compared to precorneal tearfilm

norms due to the starting lens pH of a nominal neutral pH value; if the lenses were packaged in a storage solution of a more alkaline nature near 7.45, this pattern of pH adjustment would not be exhibited. In any event, the obtained data do not support the use of this system as a useful indirect monitor of corneal pH changes related to hydrogel lens wear. However, the methodology does support data suggesting that the pH of the precorneal tear film is very near 7.45.

The fact that both types of lenses chosen for use in the protocol were packaged in neutral, or near neutral, solutions may be significant. It is possible that hydrogel stability and physical performance parameters are optimum near a pH of 7. Therefore, lenses may be packaged at that pH in order to maximize shelf life. If that is the case, and the inference of decreased stability and physical performance at pHs other than neutral also is correct. Then future material research should perhaps be centered on finding polymers possessing optimal qualities at the precorneal tearfilm pH of 7.45.

Conclusions

Simple pH measurement of the anterior lens surface does not appear to provide clinically useful information, although it does confirm normal precorneal tear pH values established by others. A question can be raised concerning the susceptibility of lens physical performance to external influence by the physical state of the hydrogel material after 2 days or more extended wear. Future polymer research may isolate materials less influenced by the precorneal environment.

Hydrogel lens water content

Introduction

Soft lens behavior, after initial placement on the surface of the eye, has been shown to change over the first 24 hours of wear. Clinically, hydrogel lenses appear to "tighten" over the first day or two of wear, necessitating a 24- to 48-hour followup examination to ensure an adequate fit is obtained by the patient. This process has been attributed to a drying or dehydration of the soft lenses as a function of initial wearing time. Since the major proportion of hydration change in those studies occurred within the first several hours, it was assumed that water content stabilization developed by the end of one day of continuous lens wear. All of these reports used only one means of water content determination without method cross-comparison, although the specific method used in each study varied. Therefore, the purpose of this portion of the overall research protocol was two-fold: to describe the dehydration course over 7 days of wear for both lens types used, and to compare two methods of water content determination in the 58 percent lens.

Methods and materials

Forty-one myopic subjects, wearing corrections that varied from -0.50 diopters to -3.50 diopters were followed on a quarterly basis for approximately 1 year. Subjects wore their soft lenses on an extended wear, disposable paradigm, with a maximum wearing schedule of 7 days/6 nights. After this schedule, lenses were removed and discarded, and at least one sleep period was spent lens-free. One hundred and ninety-six data entries were obtained on periodic followup examination over a 1-year period.

The gravimetric determination of water content was obtained by way of a analytical scale enclosed in a controlled environmental chamber kept at 35°C. The change in lens weight from the fresh, wet state to the completely dehydrated state could be used to calculate the beginning water content once reference standards were established. All 38 percent lenses were measured by this method of appraisal of <u>in situ</u> hydration level. Half of the 58 percent lenses were measured via this methodology by using one lens from each subject.

The refractive method used a refractometer (Marco*) with a fixed scale (based on one specific index of refraction) to measure the lens against. The refractive scale ranged from 35 to 75 percent water. The 38 percent lenses could not be measured with this method because they tended to drift just below 35 percent water with any amount of wearing time. Half of the 58 percent lenses were assessed by the refractive method by using one lens from each subject. In this manner, a correlation between the two methods could be established for the 58 percent water content lenses.

Results and discussion

A logarithmic water content decline occurred over the time period tested by both measurement systems (Figure 26). An independent analysis of variance for water content factored by days wear was highly significant ($p<0.001$). The largest decrease was from day 0 to day 1, with a slower decrease occurring to day 4. Specific statistical groupings at the 0.05 level of significance were: day 0; days 1 and 2; and days 3-7. Figure 26 highlights the apparent stabilization developed by day 4 extending through day 7. Contrary to suggestions of 24-hour hydration stabilization made by other investigators, these data demonstrate long-term dehydration occurring over the first 3 to 4 days of wear. In addition, the two methods of water content determination agreed remarkably well, correlating with each other at a Pearson coefficient of 0.96.

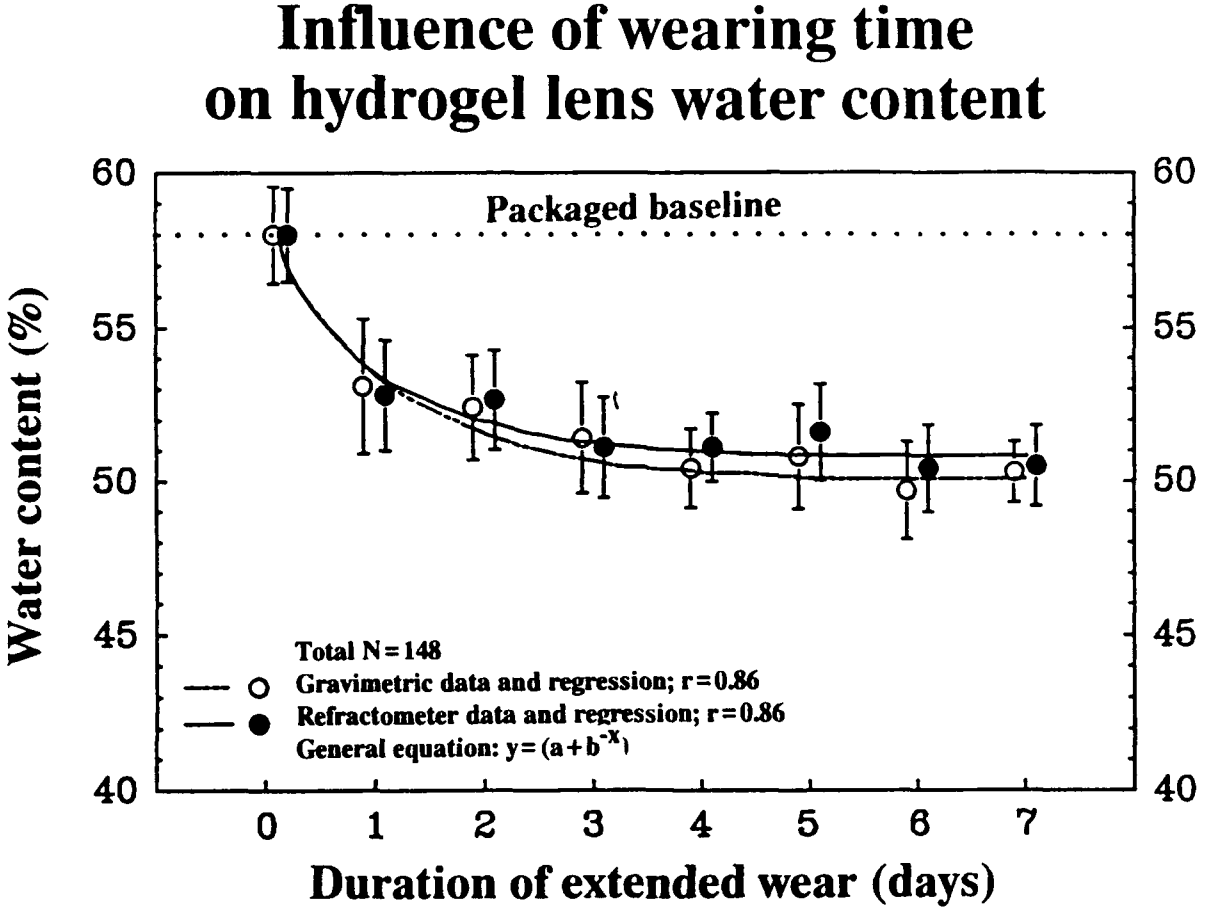


Figure 26. Influence of wearing time on hydrogel lens water content (two measurement methods; 58 percent water content lenses only).

Refractometer data on 58 percent water content lenses were initially being gathered in the summer of 1990. A number of subjects seen at Fort Rucker were deployed to Saudi Arabia on Operation Desert Shield. In order to meet the requirements of the research protocol, the subjects were given a quarterly followup exam in Saudi Arabia in November 1990. As a part of the exam, water content data were obtained using the refractive method (Figure 27). After 6 to 11 weeks "in-country," the subjects exhibited the same pattern of lens hydration, as a function of duration of lens wear, as they had at Fort Rucker. Data obtained were for 1, 2, 6, and 7 days of wear. In and around Saudi Arabia, it seemed that soft lens wearers fell into two groups: those who maintained their habitual wearing schedule of 6 or 7 days with no problems, and those who decreased their wearing time to 2 or 3 days of wear because of changes in comfort or clarity. The notion of soft lenses excessively dehydrating in the desert were shown to be erroneous by the data, but the

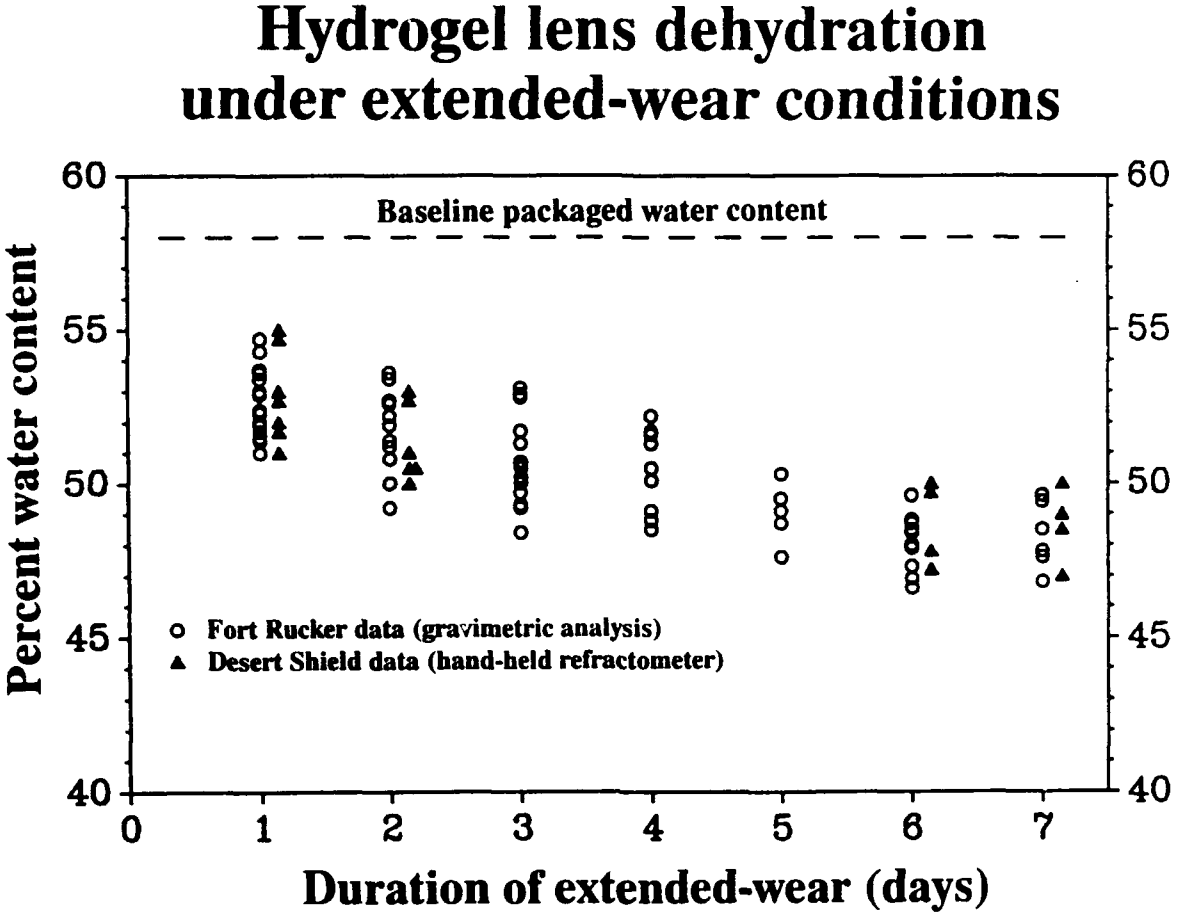


Figure 27. Hydrogel lens dehydration under extended-wear conditions (Fort Rucker and Desert Shield data).

altered wearing behavior may be indicative of an undetermined factor. In addition, there may have been excessive dehydration on initial deployment, but by 6-11 weeks some sort of adaptation apparently had occurred which returns contact lens hydration levels to the previously established physiological norm.

The 38 percent water content lenses, as measured by the gravimetric method only, exhibited an approximate logarithmic decline in hydration level with continuous or extended wear. However, the statistical picture was not as clear as with 58 percent water content lenses; although the ANOVA of water content over wearing time was significant ($p<0.01$), the groupings broke out somewhat differently than for the 58 percent lenses. Day 0 was separate from days 2-4, which were in turn distinct from days 5-7. Rather than stabilizing after a certain period of time, the 38 percent lenses dehydrated in an almost linear fashion if the first 24 hours of wear are omitted from consideration (Figure 28).

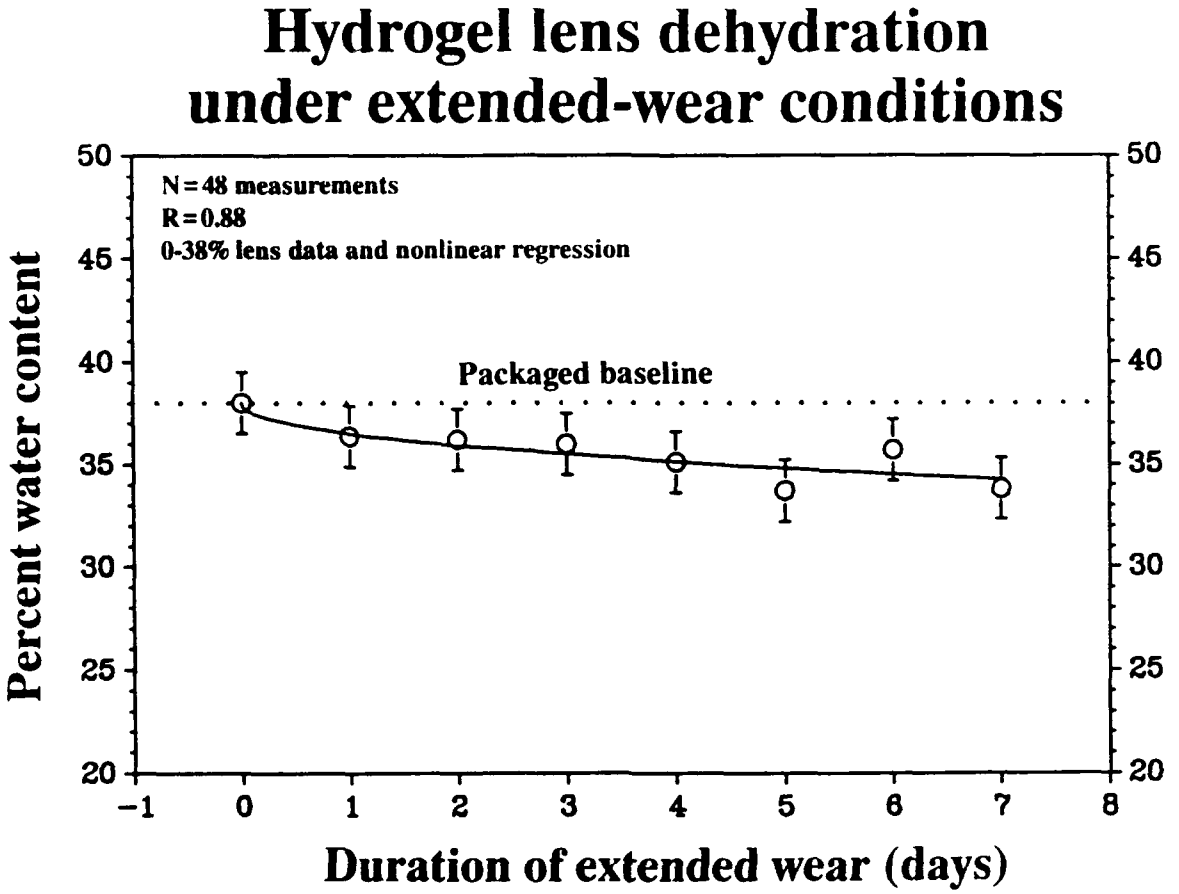


Figure 28. Hydrogel lens dehydration under extended-wear conditions (38 percent water content lenses).

Figure 29 depicts the results of the two lens types as measured gravimetrically. The amount of water loss is greater in the higher water content lens. Also the regression curve appears somewhat different between the two types. A gross examination suggests that the relative dehydration, based on packaged baseline as the norm, may be approximately the same for both lens types. However, Figure 30 reveals the 58 percent lenses to possess a greater degree of relative dehydration. The two data sets are significantly different by ANOVA ($p<0.01$). The differences in rate and degree of lens dehydration in situ perhaps can be explained by the chemical structure differences between the two lens types. The 38 percent lens is a nonionic lens, while the 58 percent lens is ionic. The degree of molecular water attraction, and differential forces resistant to water loss readily could account for these documented differences.

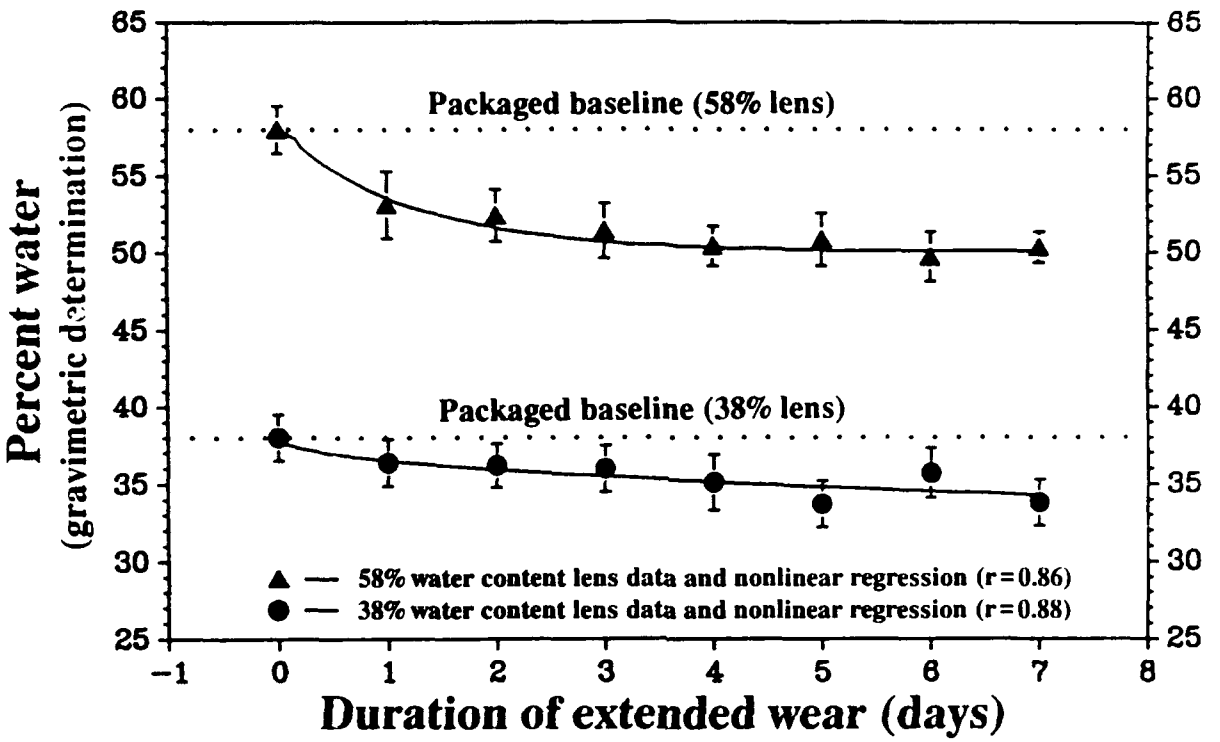


Figure 29. Hydrogel lens dehydration under extended-wear conditions (by lens type).

Clinically these differences can be applied to patient management issues. Ostensibly, a patient with decreased serous tear component production would be less likely to tolerate, or be comfortable with, an ionic lens of mid- to high-water content that presents a large hydration challenge to the eye in the initial 3 to 4 days of extended wear. The low water content, nonionic lens would provide greater comfort throughout the entire lens wearing cycle. Conversely, a patient with either adequate, or abnormally copious serous tear production would be immediately more comfortable in a mid- to high-water content, ionic lens. Therefore, the type of lens prescribed could be completely dependent upon the serous characteristics of the precorneal tearfilm.

Possible factors contributing to the long term dehydration process include: lipid and protein deposits during wear and changes in pH (anterior and posterior). Gravimetrically, the former would serve to increase the dry material weight a greater

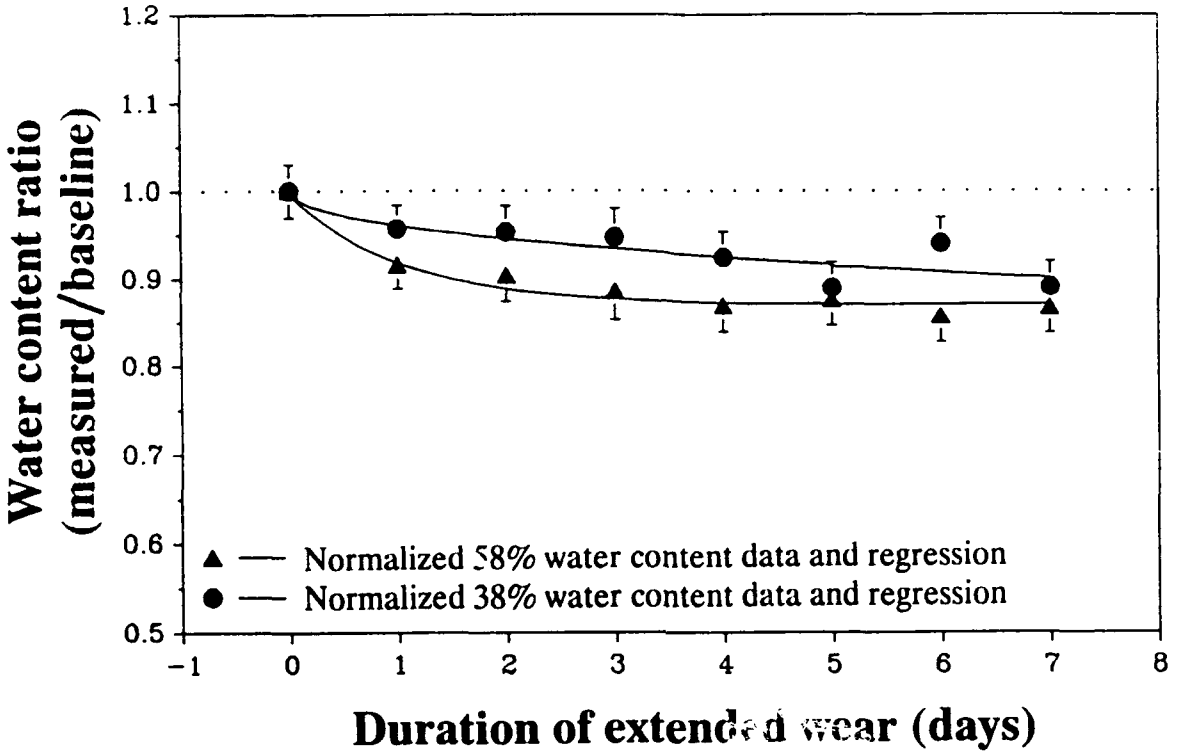


Figure 30. Normalized hydration levels in two types of soft lenses.

proportion than the wet material weight, thereby skewing the measurement in the dehydrated direction. However, there should be no refractive influence by surface lipids and proteins. The excellent correlation between the two methods tends to rule out lipid and protein deposition as contributing to the dehydration process. Materials sciences have shown a pH change in hydrogel solution to directly influence material water content (McCarey, and Wilson, 1982) and is, therefore, the likely in situ cause for lens dehydration. However, a correlative model of this suggested in situ relationship has not yet been published.

Possible contaminating factors in the methodology could include: oil from fingers on lens removal, and fluid loss during the weighing and/or refractive processes. Each could influence both methods in the same fashion; therefore the presented levels of lens hydration may slightly overestimate the amount of dehydration with wear. However, the relative relationship

between the two methods would be unaffected; the same holds for the process of long term change. The affect of any contamination error simply would decrease overall magnitude across the board, but not the basic characteristics or patterns of the processes.

Conclusions

The gravimetric and refractive methods of lens water content determination agree closely for the 58 percent water content lenses tested. Functional lens parameters, no matter the material characteristics, are in a state of flux as indicated by the change in water content over time. However, the exact pattern of change apparently is dependent upon lens material characteristics. It is probable that hydration change is a result of tear pH influences acting directly on the hydrophilic material. Extended hydrogel lens wear is clearly a complex, dynamic process for both the lens and cornea. A limited understanding of one parameter is not enough for the successful practice of contact lens care. An integrated picture of multiple parameters is necessary to reliably quantify potential limits of extended hydrogel lens wear. Therefore, specific knowledge of a patient's condition, combined with an understanding of precise lens material behavior, is necessary to maximize fitting and wearing success rates.

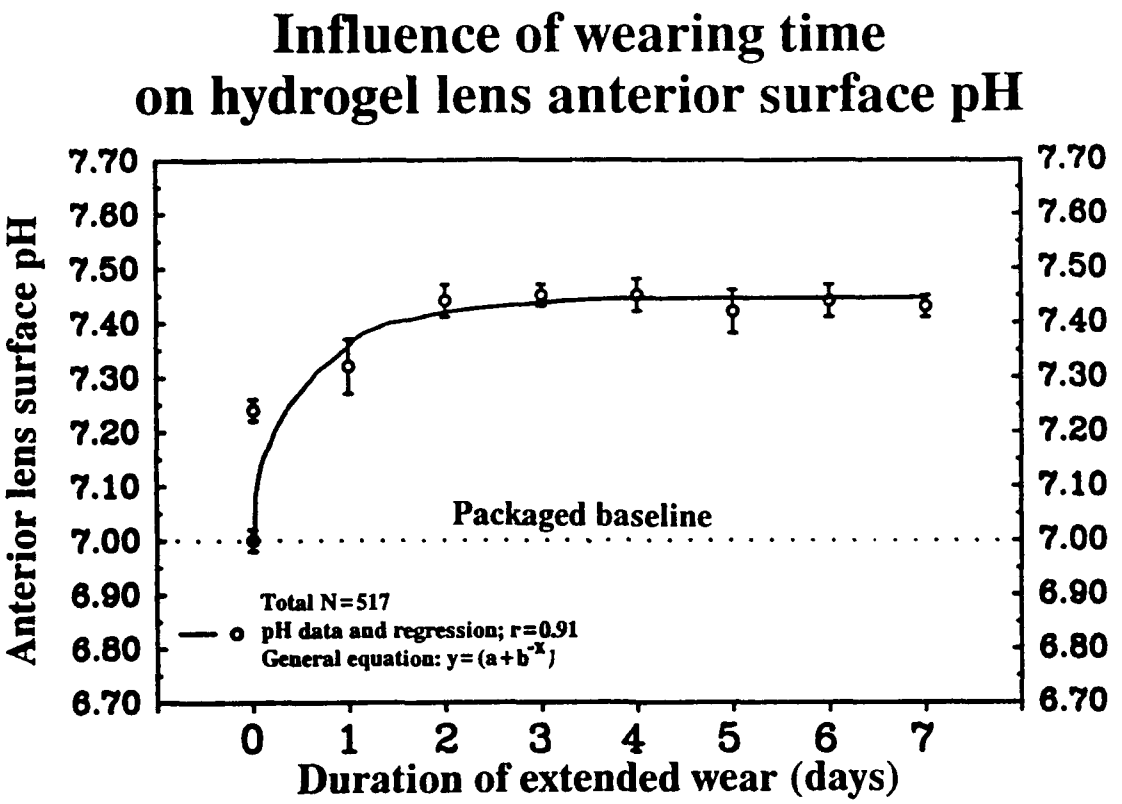
pH and water content correlational analysis

Introduction

Other investigators have shown that soft lens hydration is directly influenced by the pH of its solution *in vitro*. In addition, data from the previous sections in this report revealed both a change in hydrogel lens anterior surface pH, and a change in soft lens water content as a function of wearing time. Earlier in this report, it was concluded lens hydration changes were probably influenced by the precorneal tearfilm pH. The purpose of this section is to correlate/model the change in soft lens hydration as a function of anterior lens surface pH change *in situ* over wearing time.

Methods and materials

Anterior lens surface pH and lens hydration data for both the 38 percent and 58 percent water content lenses were obtained at every examination as presented earlier in this report (Figures 31 and 32).



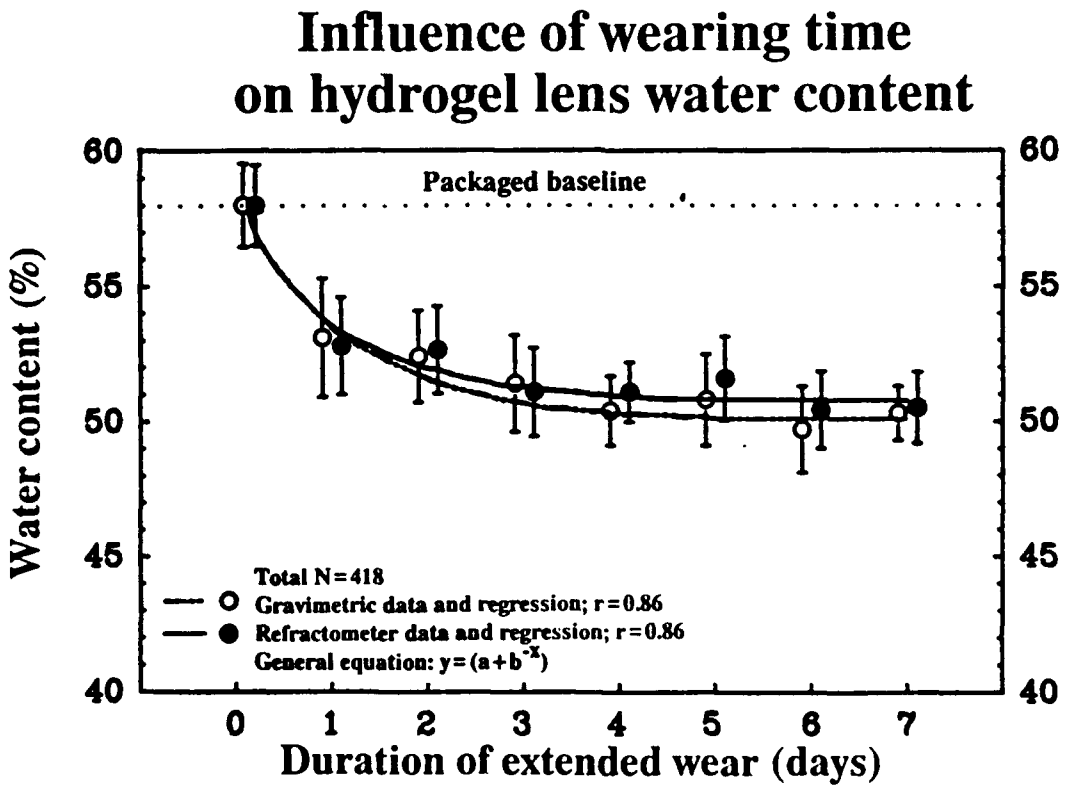


Figure 31. Influence of wearing time on hydrogel lens anterior surface pH and water content (grouped data).

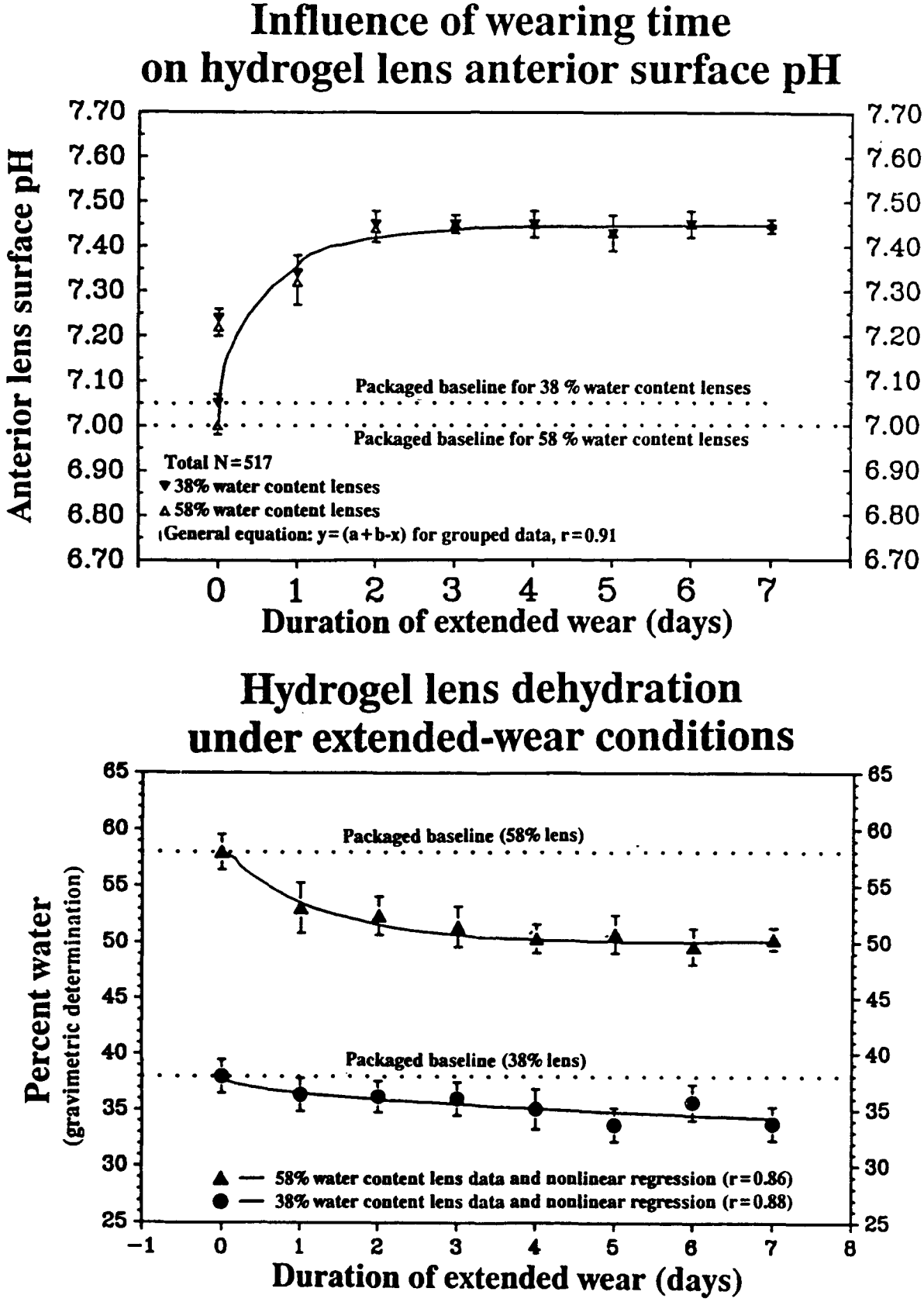


Figure 32. Influence of wearing time on hydrogel lens anterior surface pH and water content (by lens type).

Results and discussion

Using regression curves from the aforementioned graphs, the effect on soft lens hydration, in situ, by its anterior surface pH can be seen in Figure 33. The correlations for both 38 percent and 58 percent water content lenses were highly significant (R = 0.97 and 0.99, respectively) based on a linear regression model. Clearly, hydrogel water content is directly dependent on the pH of the solution within which it is suspended, clinically, the precorneal tearfilm. The slopes of the two lens types are significantly different ($p < 0.001$), apparently highlighting once more their differing ionic status and secondary ability for polar attraction of water.

If the tearfilm pH were even more alkaline, then the hydration level of worn lenses would be even less than that currently measured. Based on the endpoint values of the two lens types, it is suggested that manufacturer data on lens water content and oxygen transmissivity should specify at what pH the data were obtained. Without pH information, the functional

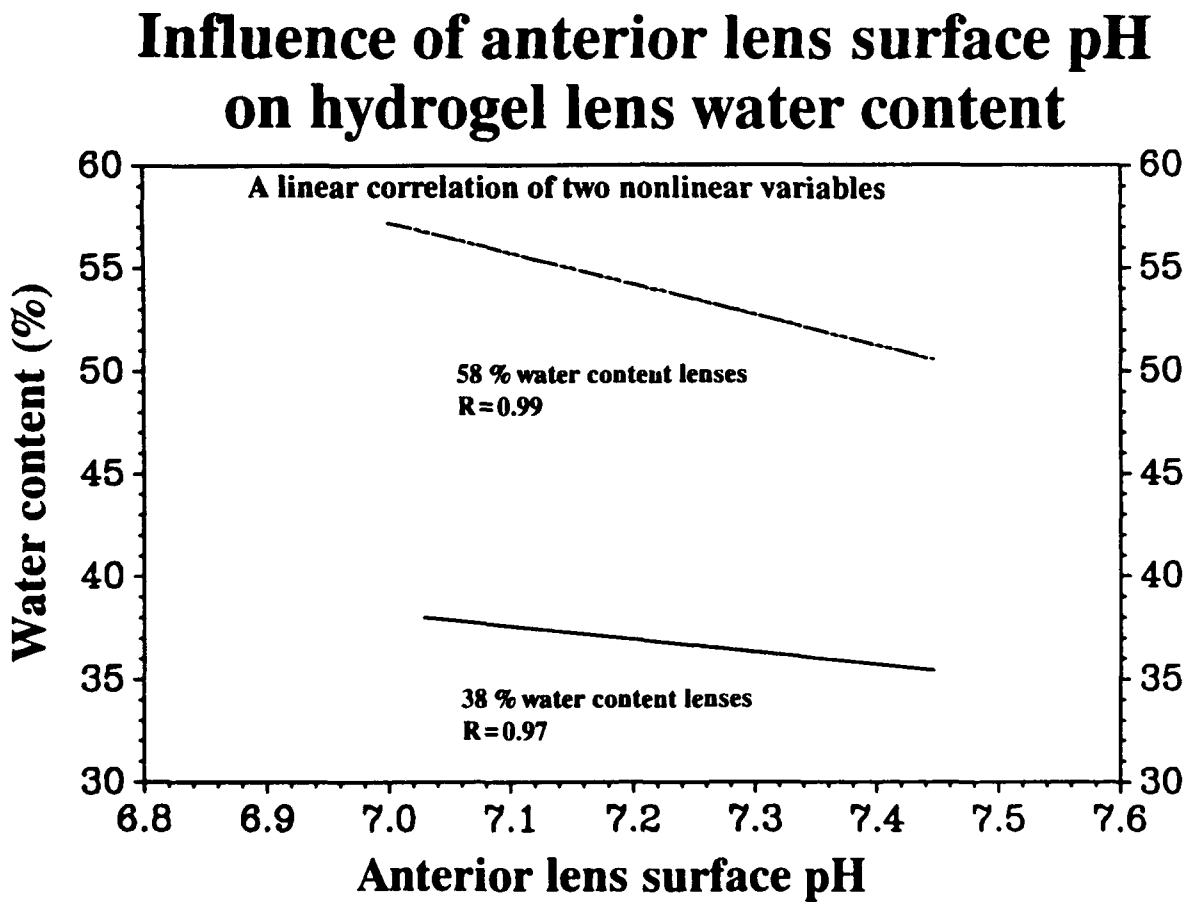


Figure 33. Influence of anterior lens surface pH on hydrogel lens water content.

performance inferences made from such data are meaningless with no useful clinical relevancy.

As an adjunct to the above, if lens manufacturers provided linear behavior models similar to Figure 33, patient care could be individually customized by the clinical measurement of precorneal tearfilm pH. Two brands of lenses, identical in all packaged parameters (power, thickness, base curve, diameter, and water content) save ionicity, would provide differing physical fits and oxygen availability on the eye, because of different *in situ* water contents.

Conclusions

Hydrogel lens water content is directly dependent on precorneal tearfilm pH. Other perceived contributors to the process (tear availability, stability, and osmolarity) likely have little clinical contribution. The clinical measurement of the precorneal tearfilm, prior to fitting a prospective patient, could assist in the lens selection process, if manufacturers provided pH-related material behavior charts.

Corneal thickness measurement differences

Introduction

Increases in central corneal thickness (CCT) associated with contact lens wear have been linked to tissue hypoxia. Corneal swelling has been induced by thick hydrogel lenses, nitrogen-fed goggles, and metabolic inhibitors. However, the degree and location of induced edema varies with the method of stress applied. The exact mechanism(s) responsible for *in vivo* soft contact lens-induced corneal swelling have not been fully elucidated. As a result, clinical modeling of corneal thickness as a function of contact lens wearing experience has not been obtained. In an effort to more fully understand the corneal stresses induced by soft contact lens wear, those subjects fitting with soft lenses only, had their CCT measured by two separate methods of pachometry at every examination.

Methods

Two methods of corneal thickness measurement were used: ultrasound pachometry, and optical pachometry. The ultrasound method uses a hand-held sensor with an ultrasound-emitting cone set at a nominal speed of 1630 meters per second. When the end of the cone is placed perpendicularly onto the apex of the cornea, the emitted sound waves are reflected back from surfaces where there is a change in refractive index (Dunn, Edmonds, and Fry, 1969), e.g. theoretically at the posterior corneal border.

The time taken for an emitted wave to traverse the cornea and reflect back to the cone is used to calculate the tissue thickness for the preset ultrasound speed. Variability in ultrasound tissue thickness measurement can be induced by interpatient variation in ultrasound velocity, point of sound reflection, and differences in tissue hydration (Salz et al., 1983; Gordon, Bogges, and Molinari, 1990).

The optical pachometry method was associated with a high magnification contact specular microscope. The contact specular microscope uses an applanation cone to flatten a specific area of the central cornea in a process similar to that used in applanation tonometry. Initially, the optical system is zeroed by focusing the microscope onto the surface of the cone. Once a clear image of the cone's surface is obtained, the cone is moved forward to applanate the central cornea. The optical system then is focused toward the subject so that a clear image of the endothelium is obtained. Since this type of specular microscope images the posterior surface of the endothelium (reference), the optical distance from cone surface to the endothelium would represent the corneal thickness. The purpose in using two different measurement techniques was merely to establish intertest reliability and document test cost/performance results.

Results and discussion

Figure 34 is a simple correlative plot of ultrasound CCT as a function of optical CCT. There was a considerable degree of data spread with a mild correlation ($R=0.56$). The two methods were significantly different by t-test ($p<0.05$). Mean ultrasound CCT was 0.542 mm +/- 0.04 SD; mean optical CCT was 0.562 mm +/- 0.04 SD. A frequency histogram of CCT, broken down by both method and eye tested (Figure 35) highlights the essentially normal distribution of the results and the different central tendencies of the two pachometry techniques.

Since the two techniques did not correlate well, a further analysis of the data was indicated. A 2-way analysis of variance (ANOVA) of CCT by method and long-term lens wear experience revealed some surprising differences ($p<0.001$; Figure 36). Initial and 24-hour exams obtained essentially like measurements, although the ultrasound technique obtained thicker CCT measurements on the initial exam. However, after 1 week in the study and longer, the ultrasound CCT measurement was progressively and significantly thinner than the optical measurements. A 2-way ANOVA of CCT by method and number of days current lens wear revealed a very similar relationship, although the maximum mean difference was not as great as for length of contact lens wearing experience ($p<0.001$; Figure 37).

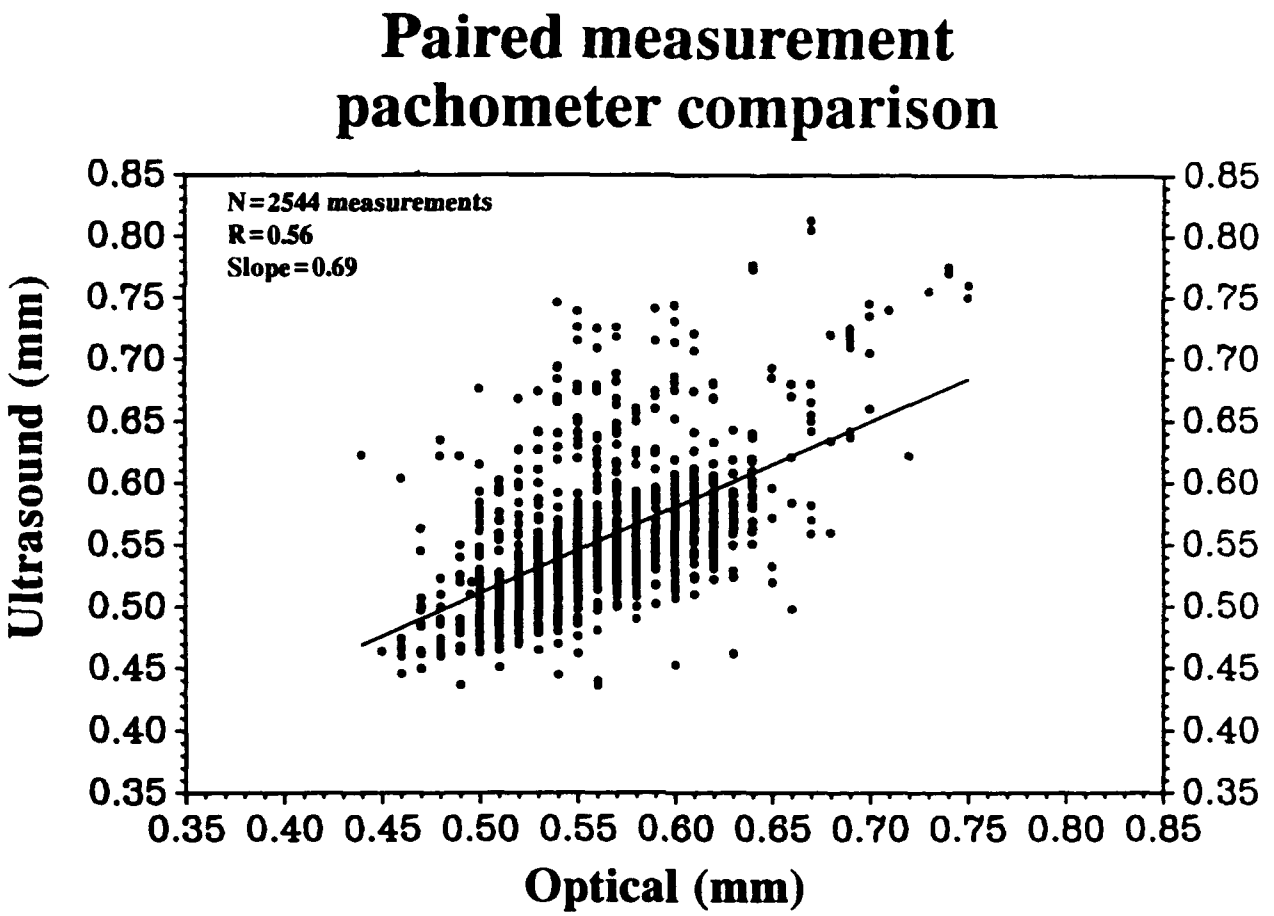


Figure 34. Paired measurement pachometer comparison.

The obvious explanation for ultrasound underestimation of CCT with current contact lens wear and overall contact lens wearing experience can be tied to an increase in corneal hydration. As hydration increases, the index of tissue refraction decreases, thereby permitting the ultrasound to travel faster, resulting in an under-calculation of tissue thickness. This can be seen in Figure 37 where number of days of lens wear on followup exam highlight the ability of the optical system to document edema. Yet, the ultrasound system fails to do so. This apparently fails to account for the constancy of CCT measurements by the optical system over the course of the study. If long-term contact lens wear made the tissue truly edematous, then the optical method should be able to directly document this. However, it should be remembered that the followup exam categories were made up of a mixture of lens wear durations. Therefore, the optical grouped data would reflect the flat linear regression it does.

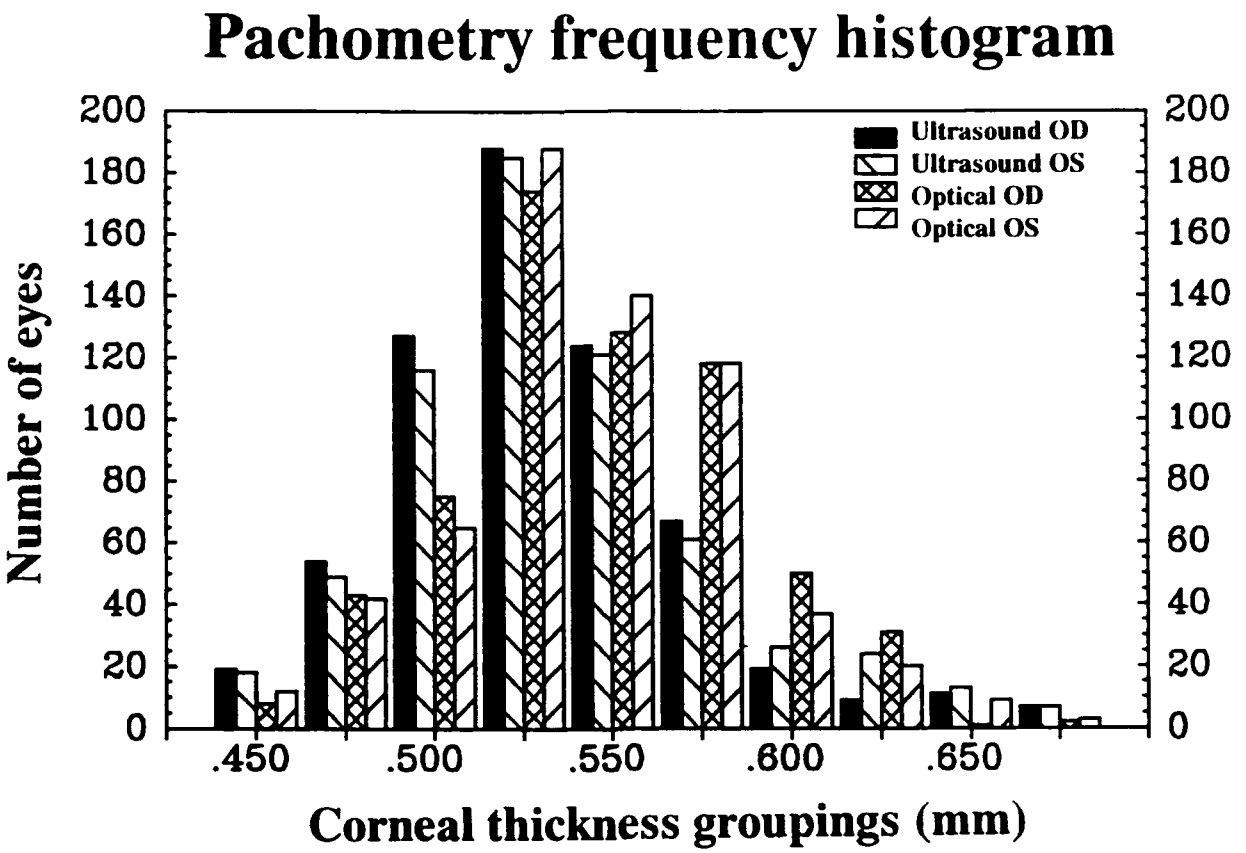


Figure 35. Pachometry frequency histogram.

Earlier contact lens studies on animal models have shown that there are a number of corneal changes associated with lens wear. These changes include: epithelial thinning, stromal tissue depletion, and increased fluid accumulation, both intra- and extracellularly. This combination of cellular tissue loss, paired with fluid accumulation within the tissue could theoretically result in a net balance in actual CCT. If this holds true, then followup exam optical measurements of CCT would remain constant. In addition, ultrasound measurements would underestimate actual CCT as a result of two contributing factors: loss of cellular tissue and abnormal fluid accumulation. Since contact lens wear has been shown to progressively influence these two factors, the progressive CCT thinning by ultrasound measurement documented in this study can thus be accounted for. Conversely, ultrasound CCT measurements consistently overestimate corneal thickness in the initial and no lens wear categories. This implies that in the relative absence of clinical edema, ultrasound methods slightly overestimate actual CCT.

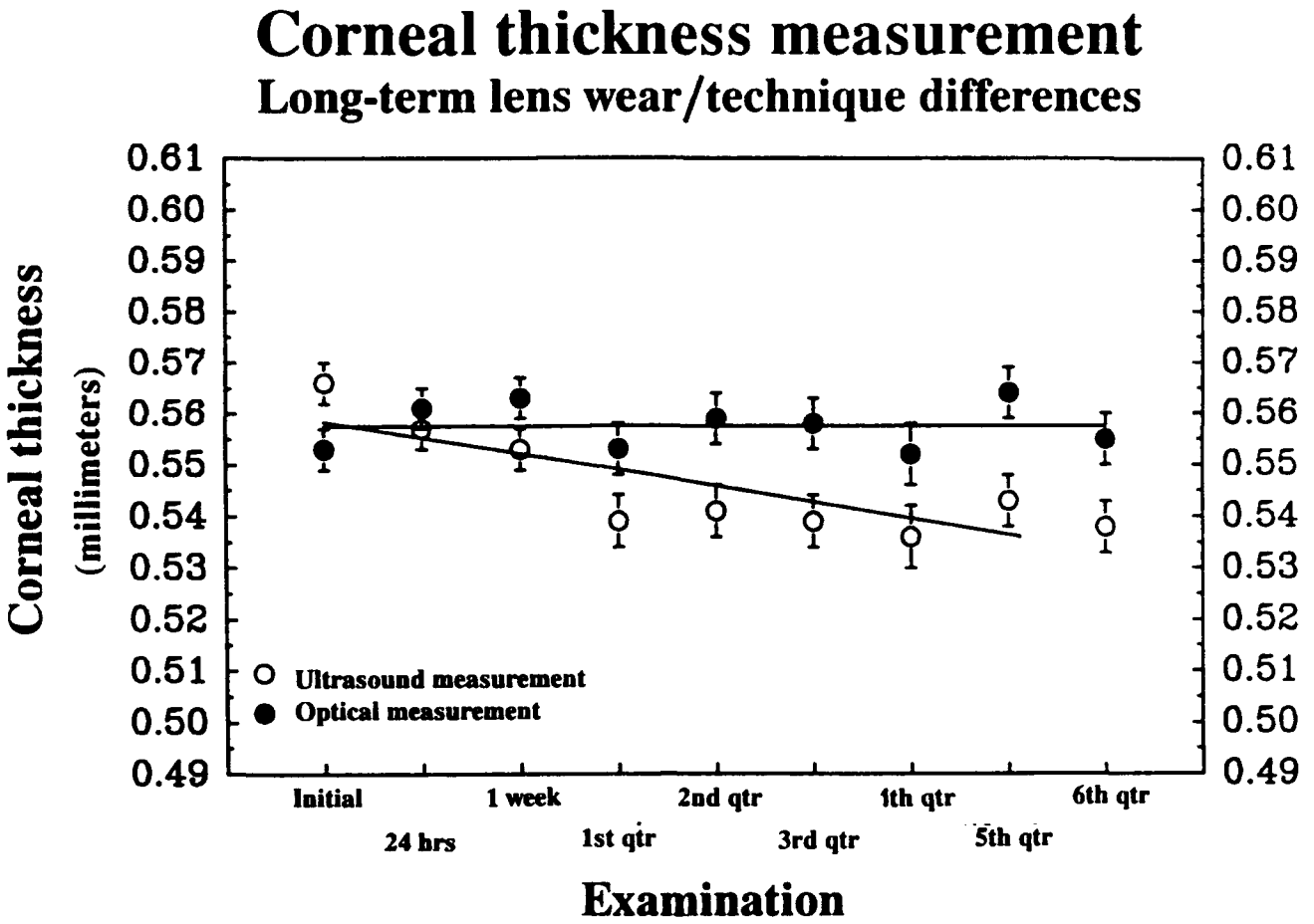


Figure 36. Corneal thickness measurement: long-term lens wear/ technique differences.

Conclusions

Based on these data, the ultrasound method of documenting CCT in contact lens wearing subjects is not an adequate means of modeling actual corneal thickness. As such, its clinical utility in a contact lens practice is questionable unless a means of correcting for this bias or error is made available. Similarly, use of an ultrasound system to monitor corneal thickness postoperatively may not be appropriate because of this presumed hydration-related bias. Surgically stressed corneas may actually be more swollen than the ultrasound system indicates. Indeed, a literature review supports this hypothesis (Nissen et al., 1991). The optical method appears not to be influenced by these sources of error, and is therefore recommended for use in contact lens and postsurgical practice.

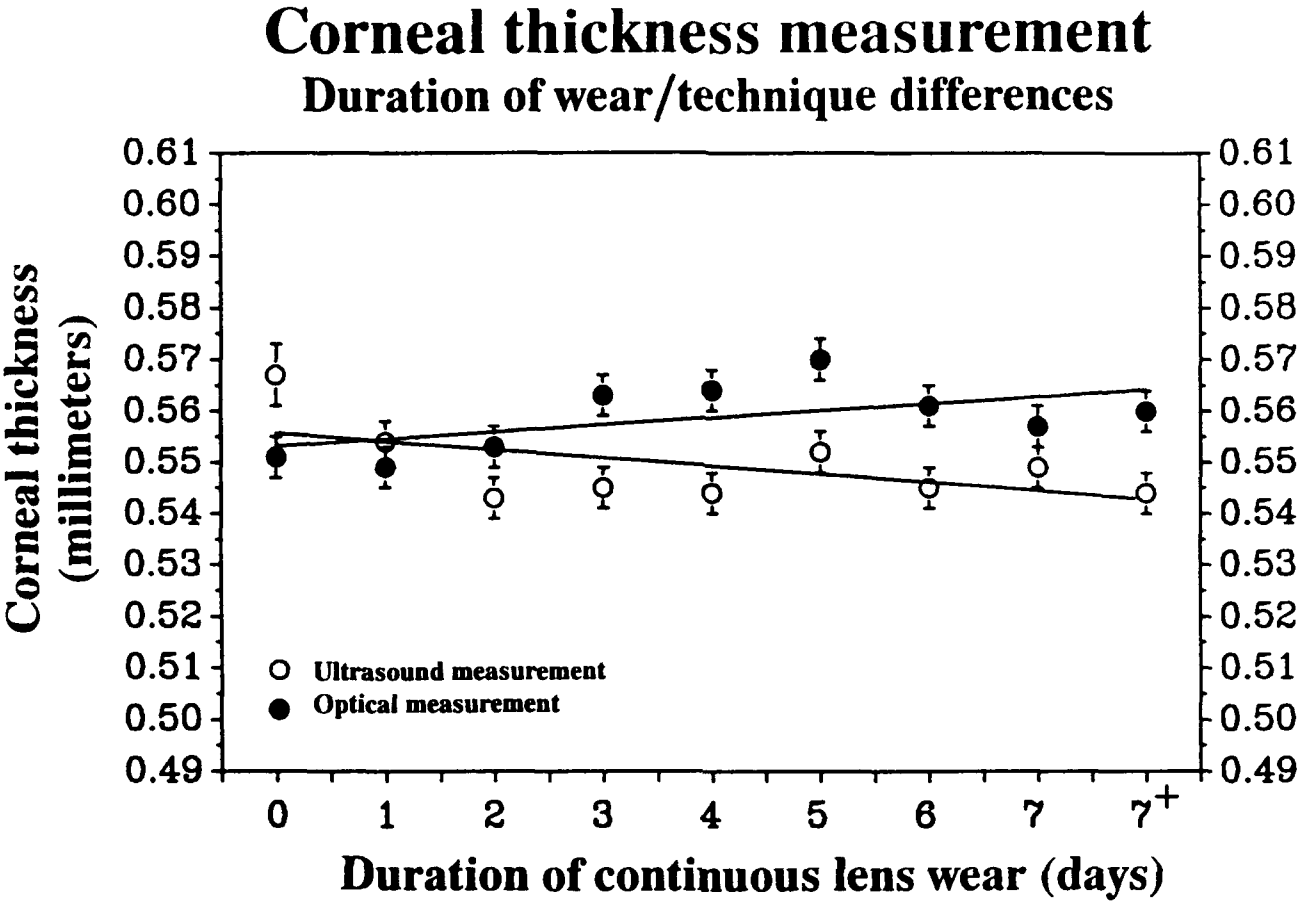


Figure 37. Corneal thickness measurement: duration of wear/ technique differences.

Of further concern is the routine use of ultrasound pachometers in optical calculations associated with refractive surgical procedures. If a long-term contact lens wearer is evaluated for radial keratotomy (RK) or photo refractive keratectomy (PRK), the ultrasound bias may adversely influence the refractive outcome of the procedure. Hence, appropriate care should be taken when working with such patients to ensure CCT measurements closely reflect the actual CCT. Multiple methods of CCT analysis are highly recommended as a crosscheck against methodological bias.

Visual acuity testing

Introduction

Prospective aviation students must meet rigorous Snellen visual acuity requirements with specific refractive error

allowances. However, rated aviators have no refractive error restrictions as long as they are correctable to a visual acuity of 20/20 or better in each eye. The research protocol had to adhere to the Snellen 20/20 requirement or the volunteer subject could not be permitted to wear contact lenses. Beyond the mere administrative requirement, good vision always has been an important aviation safety issue. Therefore, safety of flight served as a strong incentive to monitor visual acuity throughout the course of the study.

Over the many years since its inception, Snellen visual acuity has served as an excellent screening tool for appraising visual function. It is still the standard for clinical visual assessment. However, a number of investigators have sought to develop a more sensitive means of assessing visual function (Ginsburg, 1984). Since the Snellen method uses high contrast, black letters against a white background, it is tapping essentially only suprathreshold function. The newer methods seek to monitor visual performance near threshold levels of function. Therefore, two different methods of visual acuity determination were used as a check against both gross and subtle changes in visual acuity associated with contact lens wear.

Methods and materials

A standard Snellen acuity projector chart was used to assess visual acuity at the start and end of each examination. In addition, a low contrast (nominally 8 percent) printed acuity chart was used at the start and end of each exam, at the same 20-foot test distance as the Snellen chart, but at a dimmer level of chart illuminance. Subjects were tested monocularly and asked to read the smallest line of letters they could see clearly and comfortably. Subjects were given credit for an entire line if they could successfully identify at least four out of six letters presented. On followup exams, entrance acuities were through contact lenses and exit acuities through the habitual spectacle correction. The reverse order occurred on initial contact lens fitting exams.

Results and discussion

Statistical data analyses of entrance and exit acuities were unrevealing. Overall visual acuity through contact lenses were not significantly different than through the habitual spectacle correction; this held internally for both Snellen and low contrast methods ($p=0.67$ and 0.52, respectively). These findings are reassuring that contact lens removal and the corneal examination procedures used in the protocol did not adversely affect the vision of test subjects. No instances, and no complaints, of postlens wear "spectacle blur" were recorded. Visual performance assessed by both acuity methods as a function

of type or brand of contact lens was also not statistically significant ($p=0.24$). None of these statistical observations were surprising, since these results represent subjects who were successful at meeting the visual acuity restriction of maintaining 20/20 visual acuity.

A surprising finding, however, is the relationship between Snellen acuity and low contrast/low illuminance acuity. Frequency histograms of all acuity responses emphasize the difference between the two tests (Figure 38; $p<0.001$). A broader frequency distribution exists for the low contrast/low illuminance test, even though under Snellen conditions all subjects are of 20/20 acuity or better. From the data, it can be seen that a pilot can possess good Snellen acuity, yet exhibit poor low contrast/low illuminance acuity. Concurrently, it is equally probable that a pilot with good Snellen acuity can exhibit or possess superior low contrast/low illuminance acuity. Snellen acuity fails to differentiate between the two extremes of the normal distribution.

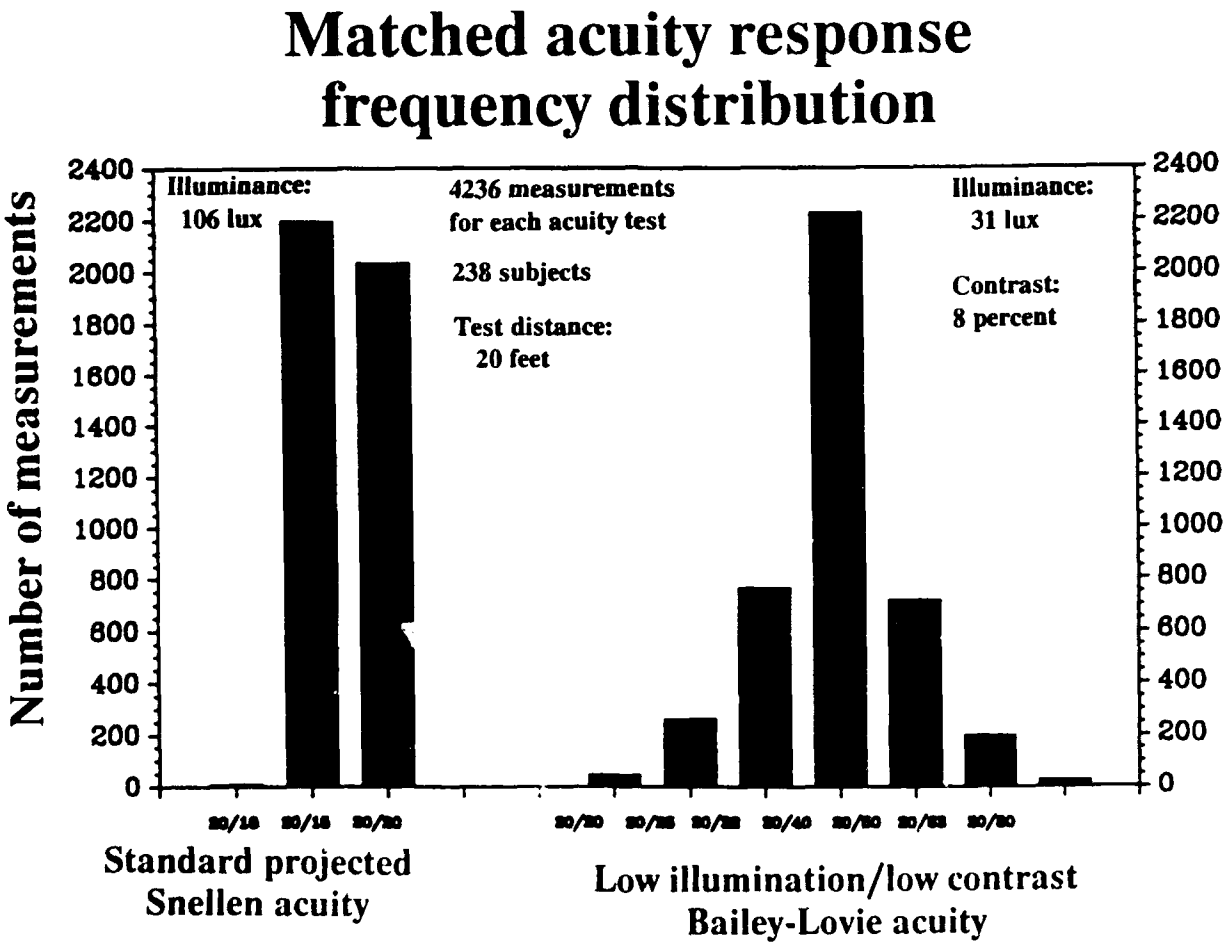


Figure 38. Matched acuity response frequency distribution.

Plots of low contrast/low illuminance acuity as a function of age, for both the spectacle and contact lens wearing conditions, demonstrate the absence of age-related, or spectacle/contact influences (Figure 39). Refractive astigmia (corrected with spectacles; not entirely corrected with spherical soft lenses) does not correlate with the low illuminance/low contrast responses, either. On the other hand, the contact lens-wearing condition correlates inversely in a marginally significant fashion (mean R = -0.12. Therefore, some of the low illuminance/low contrast acuity distribution spread is due to uncorrected astigmatism in the contact lens condition. However, a correlation of 0.12 means that less than 2 percent of the observed effect or spread is due to refractive astigmatism. Correlations by each factor are in Table 2.

Operational studies have suggested that there are superior, average, and poor visual performers with regard to target detection, recognition, and identification. However, no screening tests have been established and standardized that are capable of consistently differentiating between the groups of operational visual performers. Without paired acuity and operational testing, there is no proof that the extremes of the low contrast/low illuminance distribution would correlate or match operational visual performance. However, the advantage of being able to screen for superior visual performers prior to flight training does merit additional study.

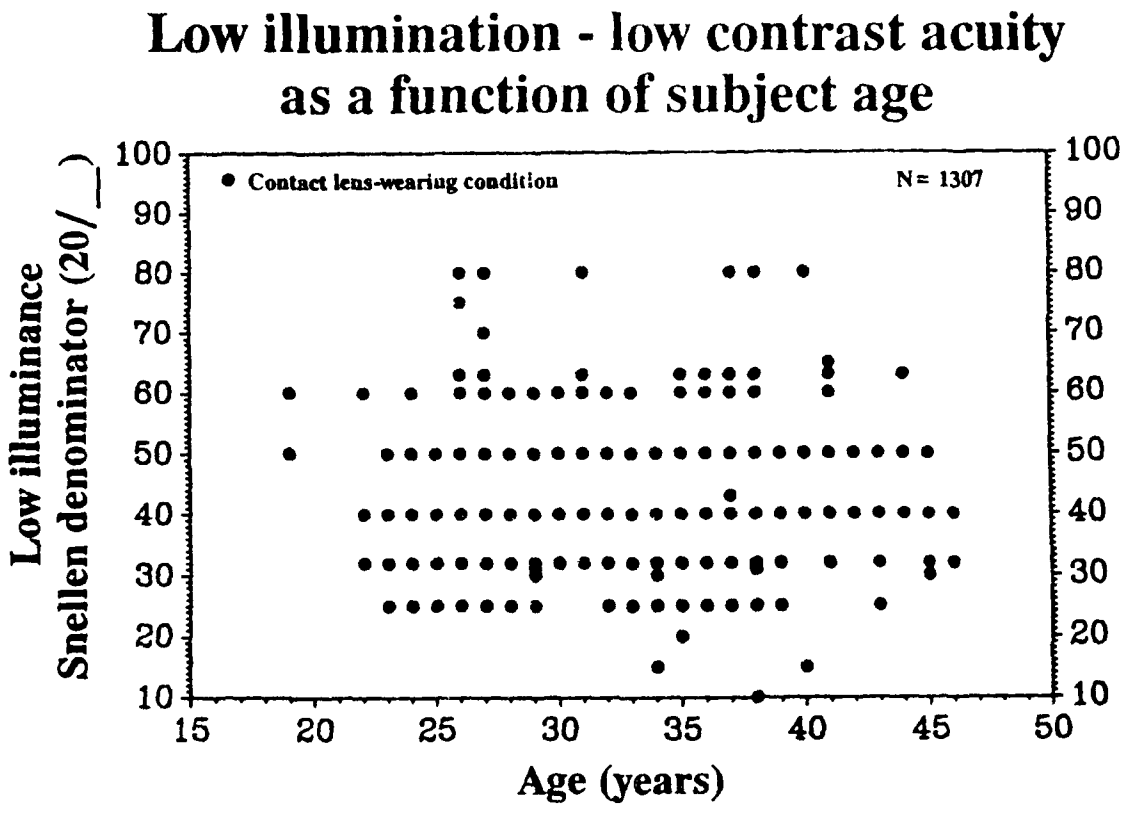
Conclusions

Internal comparisons of visual acuity by either Snellen or low contrast/low illuminance methods are not influenced by type of contact lens worn, by the use of spectacles, by age, or by entrance and exit assessment. External comparisons of the two acuity methods emphasize statistically significant differences that have potential for future use in identifying superior visual performers. If this potential is realized, then standards for visual assessment in military aviation, and the military in general, will need to be changed.

Case report: endothelial guttata

Introduction

One particular AH-64 subject, age 27, exhibited on the initial exam an endothelial appearance indicative of physiologic stress (Figures 40 and 41). Even though the standard slit lamp exam was negative, the specular microscope revealed bilateral central corneal "guttata," or dark areas scattered within the



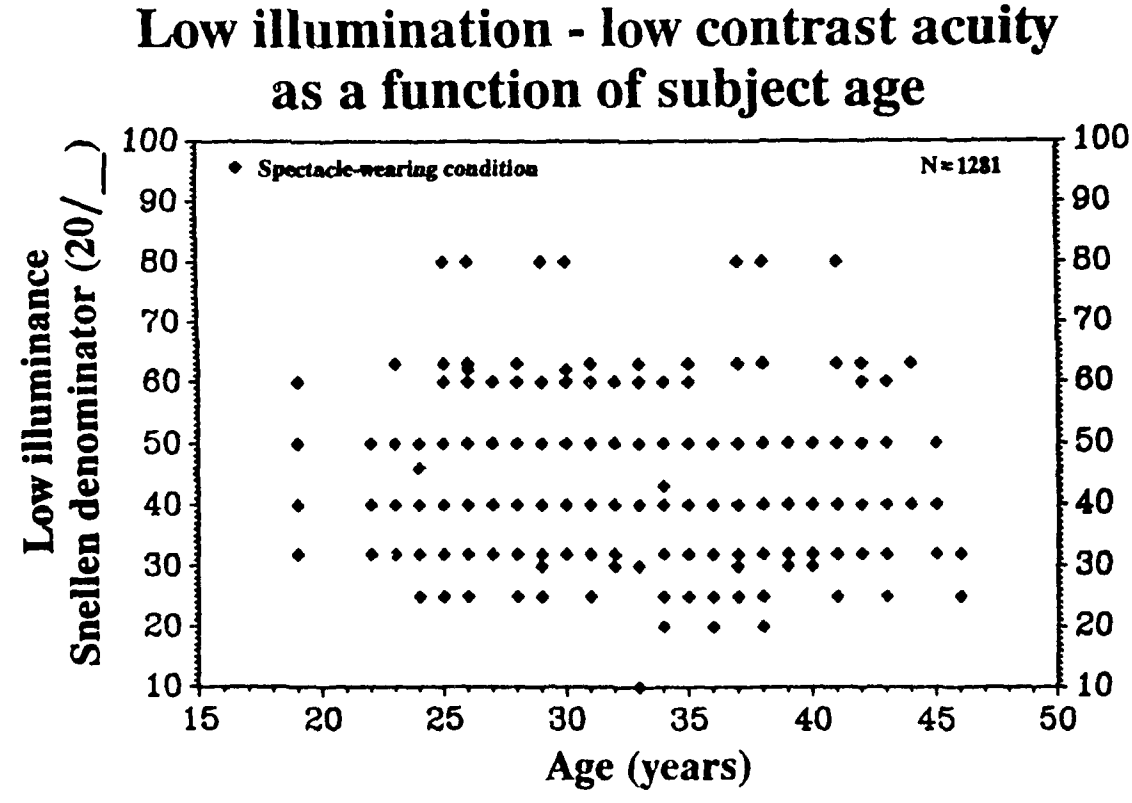


Figure 39. Low illuminance - low contrast acuity as a function of subject age (contact lens and spectacle-wearing conditions).

Table 2.

Low illuminance/low contrast acuity
Age vs acuity and correction

	OD(contacts)	OS(contacts)	OD(spectacles)	OS(spectacles)	
Age	0.02	0.02	-0.04	-0.05	{R value
	645	662	634	647	{N
	0.70	0.64	0.30	0.20	{p value
Cylinder					
	-0.11	-0.13	0.03	0.01	{R value
	152	152	152	152	{N
	0.08	0.06	0.69	0.82	{p value

endothelial mosaic. Guttata have been documented in association with a number of cornea-stressing conditions, and their presence sometimes can be contraindicative for contact lens wear.

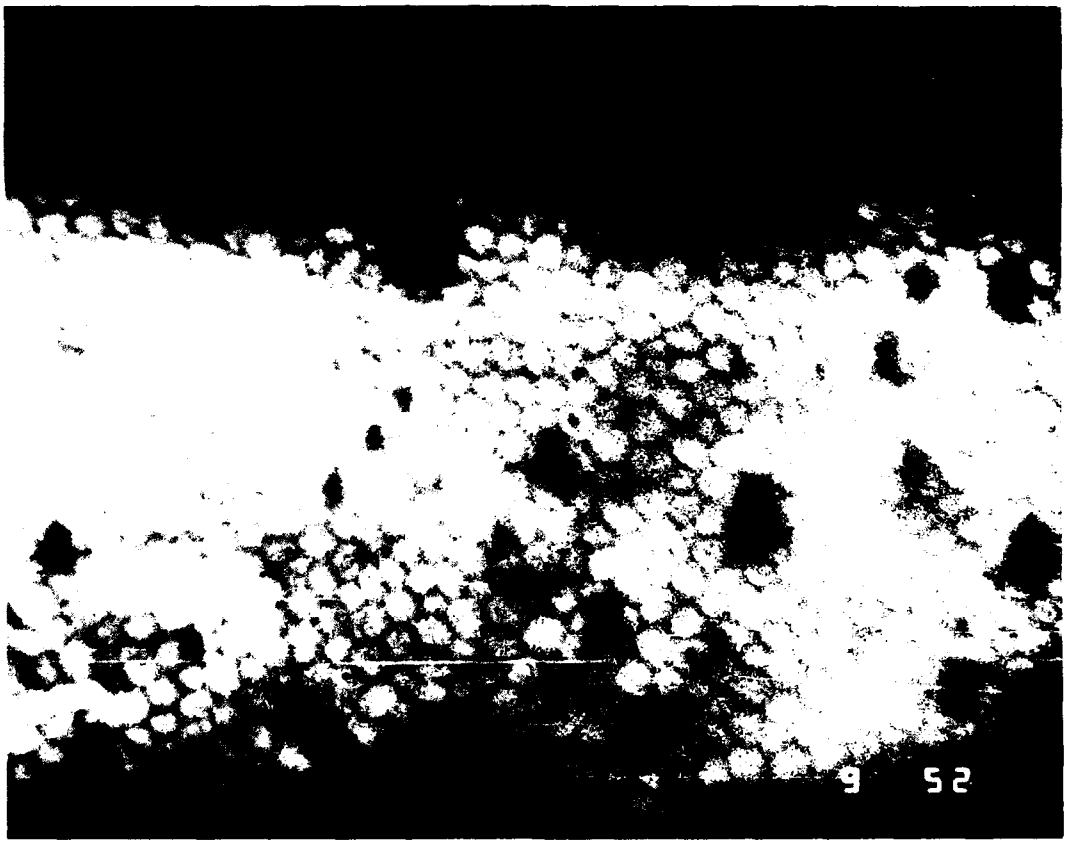


Figure 40. Endothelial photomicrograph, right eye, initial exam.

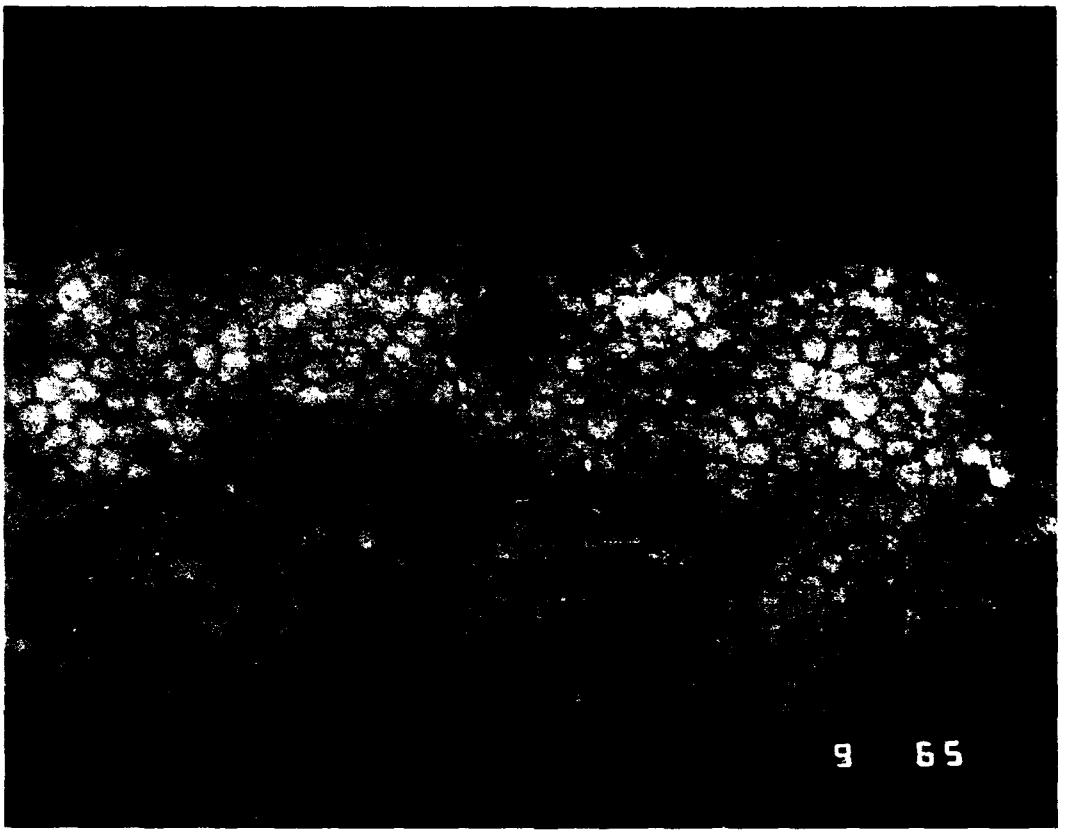


Figure 41. Endothelial photomicrograph, left eye, initial exam.

The subject was advised of the findings, and the possibility that contact lens wear could exacerbate the condition at any point during the study or even in later life. Despite this admonition, the subject reiterated his desire to enroll in the contact lens research program. His left eye was emmetropic; his right eye was slightly myopic, correctable to 20/20 visual acuity with a -0.50 D. Acuvue* lens. Specular microscopy was performed at each quarterly followup exam from August 1989 through October 1991.

Methods

A Konan-Keeler* contact specular microscope with both 35 mm and video camera attachments were used to obtain imagery of the corneal endothelium. The subject was examined under local anesthesia provided by the topical application of proparacaine hydrochloride. The 35 mm photographs were convenient for medical documentation. The video imagery was used for processing by a Topcon image net 512 endothelial analysis system*. The analyzed data are from four separate frames for each eye, electronically

"grabbed" by the image processing system on the initial and final exams. Approximately 200 central corneal endothelial cells are incorporated into each analysis. Representative frames and their preliminary border enhancement are provided in Figure 42.

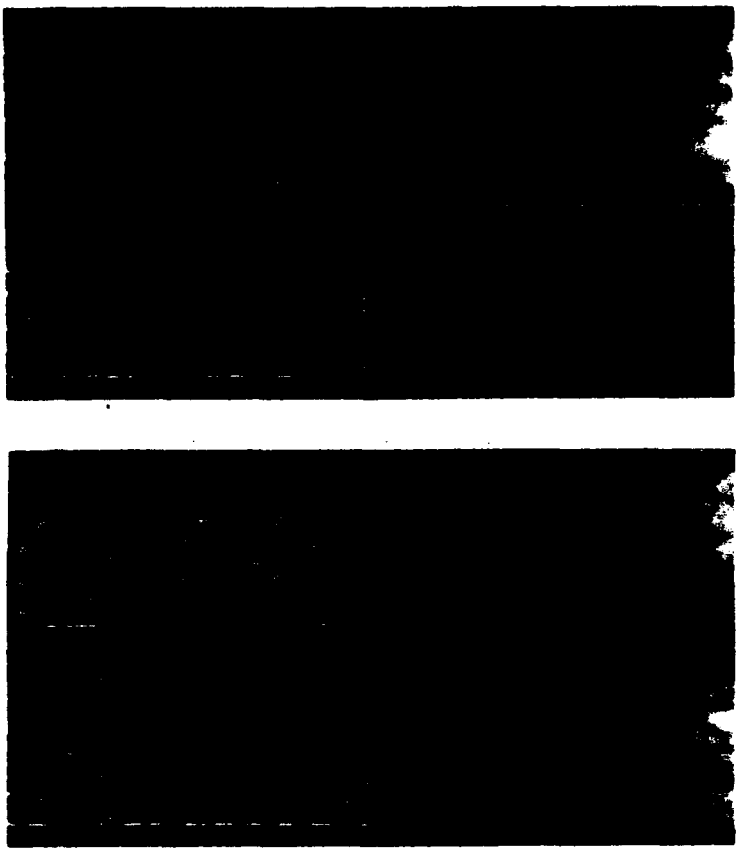


Figure 42. Endothelial analysis; initial and final exams.

Results

Figure 43 is a frequency histogram of the subject's endothelial cells from each eye, on each exam, grouped by area. There are three main points to be noted from the histogram: October 1991 data from both eyes have an excess number of very small cells (100-200 micrometers), right eye October 1991 data have significantly fewer medium-sized cells (400-500 micrometers), and right eye October 1991 data have an excess number of very large cells (800-900 micrometers). Table 3 summarizes the analysis data. Specific comparisons reveal statistically significant differences in the standard deviation, coefficient of variation, and hexagonality for endothelial cells

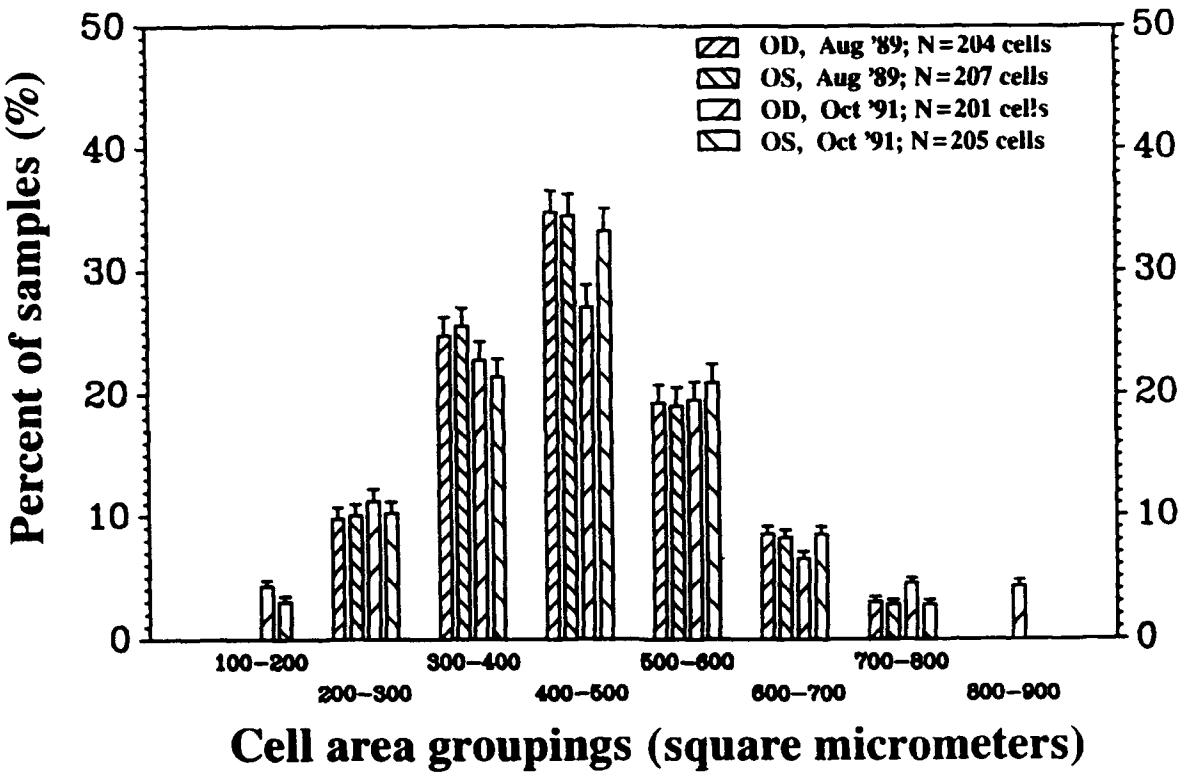


Figure 43. Endothelial cell size distribution.

of the right eye after over 2 years of soft contact lens wearing experience. For all other factors there were no significant changes, except for the smaller minimum cell size for both eyes on the final exam. Based on existing literature, all other data fall within the normal, expected ranges.

Table 3.

Endothelial analysis data

	August 1989		October 1989	
	OD	OS	OD	OS
Minimum	235.7	247.9	193.2	193.1
Maximum	716.6	722.4	864.5	726.5
Mean	449.7	453.0	440.2	458.5
SD	113.9	117.3	132.6	113.4
CV	25.4	25.9	30.1	24.7
Density	2223.7	2207.5	2272.0	2181.0
Hexagonality	44.8	44.8	42.0	44.0

Discussion

With the nonlens-wearing eye serving as this subject's control, these data verify that soft contact lens wear directly affects endothelial cell size variability as measured via contact specular microscopy. Complicating this case is the presence of central corneal guttata, which, in a contact lens wearer, sometimes can be indicative of lens-induced physiological stress. Theoretically, the presence of guttata prior to exposure to the stresses associated with contact lens wear would suggest the existence of an ongoing degenerative process. This should make the tissue more susceptible to the physiological load imposed by contact lens wear. However, data in this case report demonstrate that other indicators of endothelial pathology (mean cell area and cell density) do not significantly change over time, or as a result of contact lens wear. Indirectly then, these data suggest an apparently stable abnormality in this subject.

It is conceivable that the presence of dark, nonreflective areas of the endothelium on specular microscopy may not be a sensitive enough descriptor to differentiate basement membrane abnormalities from extra- and intracellular edema. Therefore, the physical presence of so-called endothelial guttata is not necessarily indicative of acute physiological stress or disease. These data highlight the need to be able to clinically differentiate between possible subsets of guttata in order to quickly identify those requiring immediate therapeutic attention.

Schirmer tear test

Introduction

Tear production was measured as a part of the overall physiological assessment of contact lens wear. Since the research was segregated organizationally into original protocol subjects and Desert Shield/Storm subjects, this aspect of research was additionally separated by method of tear production measurement. Original protocol subjects had the Schirmer tear test administered under topical anesthesia, while the Desert Shield/Storm subjects had the test done without topical anesthesia (there was concern about possible topical anesthetic instability in the desert heat).

Tear production measurement has always been difficult to quantify on a consistent basis. Variability can be induced by: inconstant filter paper capillary flow, and pore wettability; distinct individual irritation reflex tearing responses to topical anesthesia and/or from filter paper irritation without anesthesia; and varied tear surface tension, viscosity, and

evaporation characteristics. As a result, Schirmer tear testing has been of greater descriptive and relative comparative value that as a quantitative standard.

Methods and materials

All participants were fitted with extended wear contact lenses that were used on a flexible wear disposable basis. Duration of extended wear was individually governed by the subject based on physical comfort and/or visual acuity. Subjects ranged in age from 19 to 47. Because of combat exclusions, there were only two female subjects, so sex-based variation is not present in these data. A modified Schirmer tear test was performed on both initial and followup exams using Alcon* brand standardized sterile strips (35 mm long and 5 mm wide).

Two subject groups were used. One consisted of AH-64 "Apache" battalion and special operations aviation regiment aircrew fitted with contact lenses as part of a generalized research protocol. This group was administered the modified tear test under topical anesthesia. The second group consisted of general aviation aircrew fitted with contact lenses under the aegis of the research protocol in response to specific deployment needs related to Operation Desert Shield/Storm. These subjects were administered the modified tear test without the benefit of anesthesia because of concerns for solution decompensation at temperatures much greater than 74°F. Since many members of both groups saw service in Southwest Asia, subject crossover on followup examination from 1 group to the other did occur. However, subject crossover could be seen as a stabilizing influence helping to minimize unpaired statistical analysis error. Therefore, the data set overlaps were not truncated.

The modified Schirmer tear test varied from the accepted method in tear strip placement. The intent of the test was to determine the total amount of strip wetting possible by a subject. Therefore, in order to maximize tear capture the strips were placed just temporal to the lower lid punctum; this placement helped standardize consistent strip placement by providing a prominent physical reference point that also minimized corneal irritation.

Results

Mean tear strip wetting on all exams are recorded on Table 4. The data are broken down by original protocol vs. Desert Shield/Storm, and by type of contact lens worn. There were statistically significant differences noted between both comparisons. Figures 44 and 45 are percent distribution histograms of tear strip wetting for both initial and followup exams (Figure 44 without anesthetic, and Figure 45 with anesthetic). Test

strip wetting data were broken down into equal sized 5-mm groups. The initial, anesthetized group consisted of 258 subjects given a mean of 6 followup exams. The second, unanesthetized group consisted of 344 subjects given a mean of 3 followup exams. Statistical comparison (t-test) revealed no significant difference between initial and followup exams within each separate condition and wetting grouping. However, the with and without anesthetic sample comparison between the condition groups was statistically significant ($p<0.01$).

Discussion

A recent publication suggested contact lens wearers may produce more tears than nonlens wearers (Occhipinti et al., 1988). However, the obvious stability of the contact lens followup data compared to the initial prelens-wear data, indicates that contact lens wear does not influence tear production over time. This contradicts the observation made by Occhipinti et al. However, there was a distinct difference noted between type of contact lenses worn. The mean tear productivity

Table 4.

Schirmer tear test.

Subject group	Mean wetting(mm) +/- SD	Lens type	Mean wetting(mm) +/- SD
Original anesthetic protocol (238)	13.92[2] +/- 1.67	58% water	13.28 +/- 1.56
		38% water	14.44 +/- 1.89
		RGP	9.51 +/- 1.39[1]
No anesth. DS/S protocol (344)	20.85[2] +/- 1.72	58% water	21.34 +/- 1.98
		38% water	19.45 +/- 2.19
		RGP	none fitted

[1] $p<0.001$
[2] $p<0.0001$

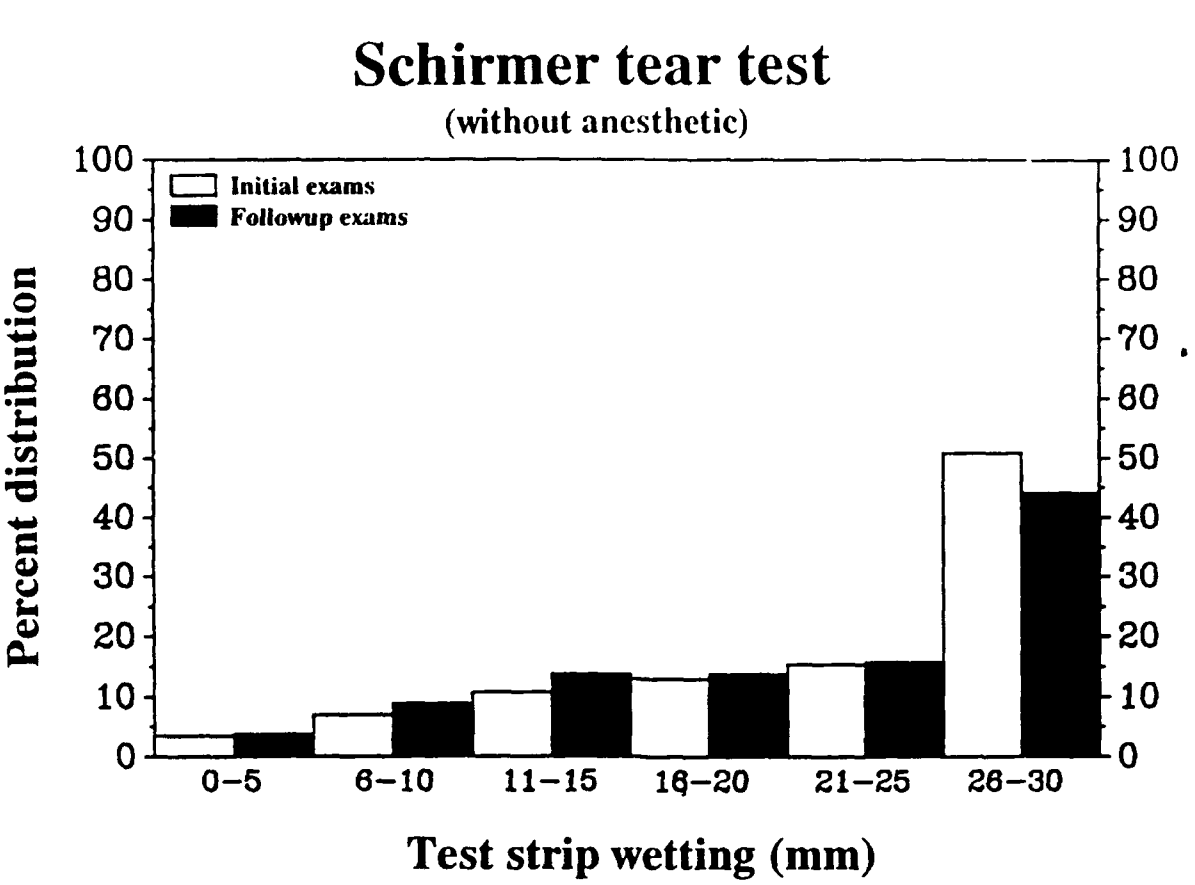


Figure 44. Schirmer tear test (without anesthetic).

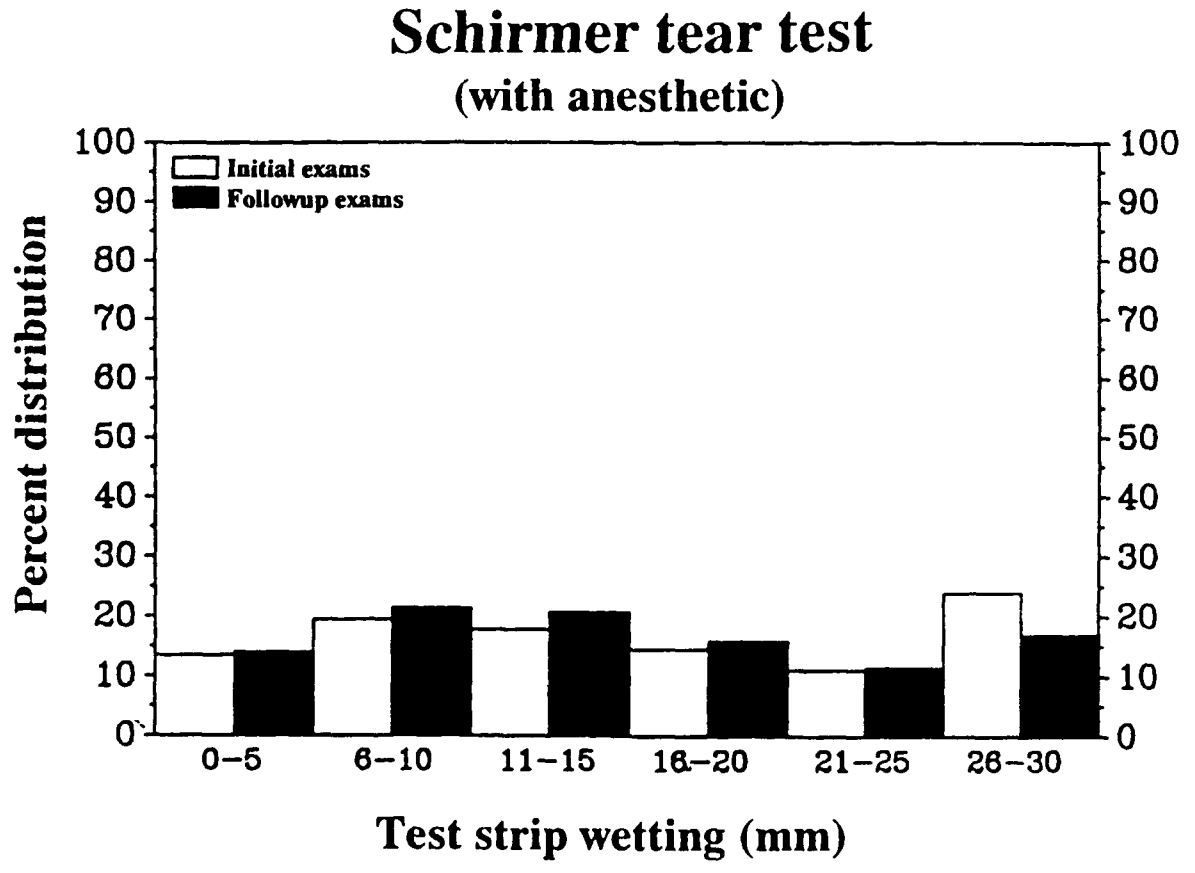


Figure 45. Schirmer tear test (with anesthetic).

of RGP lens wearers was significantly less than that of the soft lens wearers. RGP fits were conceptually reserved for subjects with a spherical equivalent of plano, and for high astigmats. It is possible there was a bias toward dry eye subjects, as well; otherwise, it must be concluded that RGP lens wear is less tear-stimulating than soft lens wear.

From Table 4, we see mean strip wetting was significantly greater for the without anesthetic condition or group. This is graphically illustrated by the low percentage of subjects falling within the 0-5 mm wetting block and the large percentage of subjects falling in the 26-30 mm wetting block in the "nonanesthetic condition" creating a skewed orientation across the test strip wetting groupings (Figure 44). On the other hand, subject distribution in the "with anesthetic condition" is more evenly distributed across the test strip wetting groupings (Figure 45).

These descriptive distinctions highlight the advantage of topical anesthesia in test administration. Failure to use an anesthetic will bias the data toward higher values as a result of reflex tear production. This observation is supported by noting that the percentage exhibiting 0-5 mm wetting "with anesthetic" was over three times greater than "without anesthetic." This indicates the relative requirement for topical anesthesia in order to identify or isolate a truly chronic dry eye. In conclusion, the Schirmer tear test has clear categorical value in comparing specific groups and conditions.

Operations Desert Shield and Desert Storm

Introduction

In September 1990, the general aviation version of a developmental chemical protective mask was identified for early fielding in Southwest Asia without an available spectacle outsert. The Army Surgeon General, in response to an Aviation Systems Command (AVSCOM) request, granted a blanket waiver to existing regulations so that all aircrew deploying to Southwest Asia could be fitted with contact lenses. Therefore, all ametropic aircrew (pilots, crewmembers, maintenance personnel, and medical support personnel) deploying to Southwest Asia were examined on a volunteer basis for possible contact lens wear under the aegis of the ongoing Armywide contact lens research protocol. Specific data on aircraft, aircrew job distribution, and age are provided in Figures 46-49.

Eleven Army optometrists and 11 Army ophthalmic technicians performed the additional examinations at over a dozen U.S. locations and 3 locations in Europe. Four of the teams permanently deployed to Saudi Arabia in direct support, and for

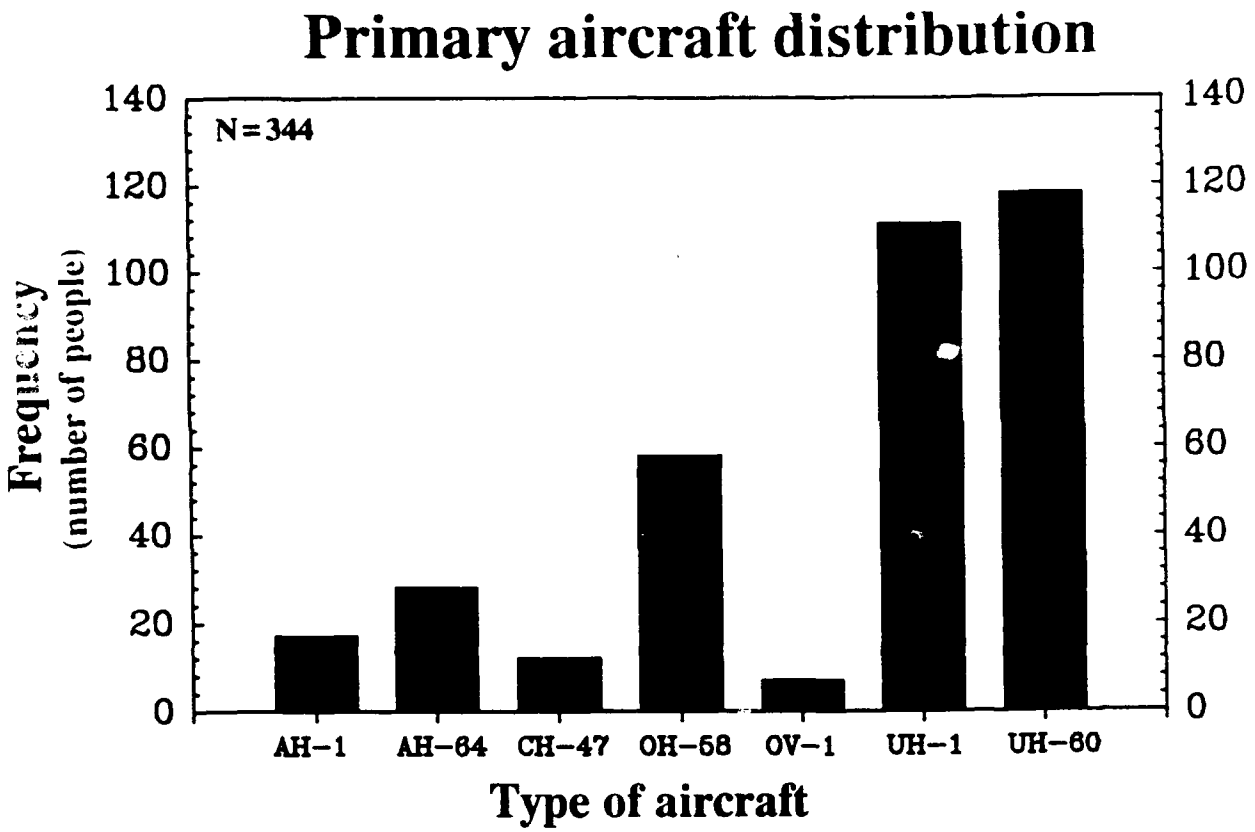


Figure 46. Primary aircraft distribution.

the duration, of Operation(s) Desert Shield/Storm. The original Armywide Apache and Special Ops protocol included 238 subjects, while the Desert Storm portion (general aviation) added 344 subjects. Approximately 450 of the 582 contact lens-wearing subjects served in Southwest Asia on Operation(s) Desert Shield/Storm.

Methods and materials

Every volunteer subject was given an initial, 24-hour, and 1-week examination at the location of deployment mobilization. The basic exam included refraction and visual acuity, slit lamp examination, tear BUT assessment, and a Schirmer tear test (without topical anesthesia). Lens application and removal training were provided after accomplishment of a successful fit. Quarterly followup exams were conducted on-location in Saudi Arabia. Twelve weeks of materials (48 lenses and 4 boxes of unit dose wetting solution) were issued at the 1-week exam and after each quarterly followup exam.

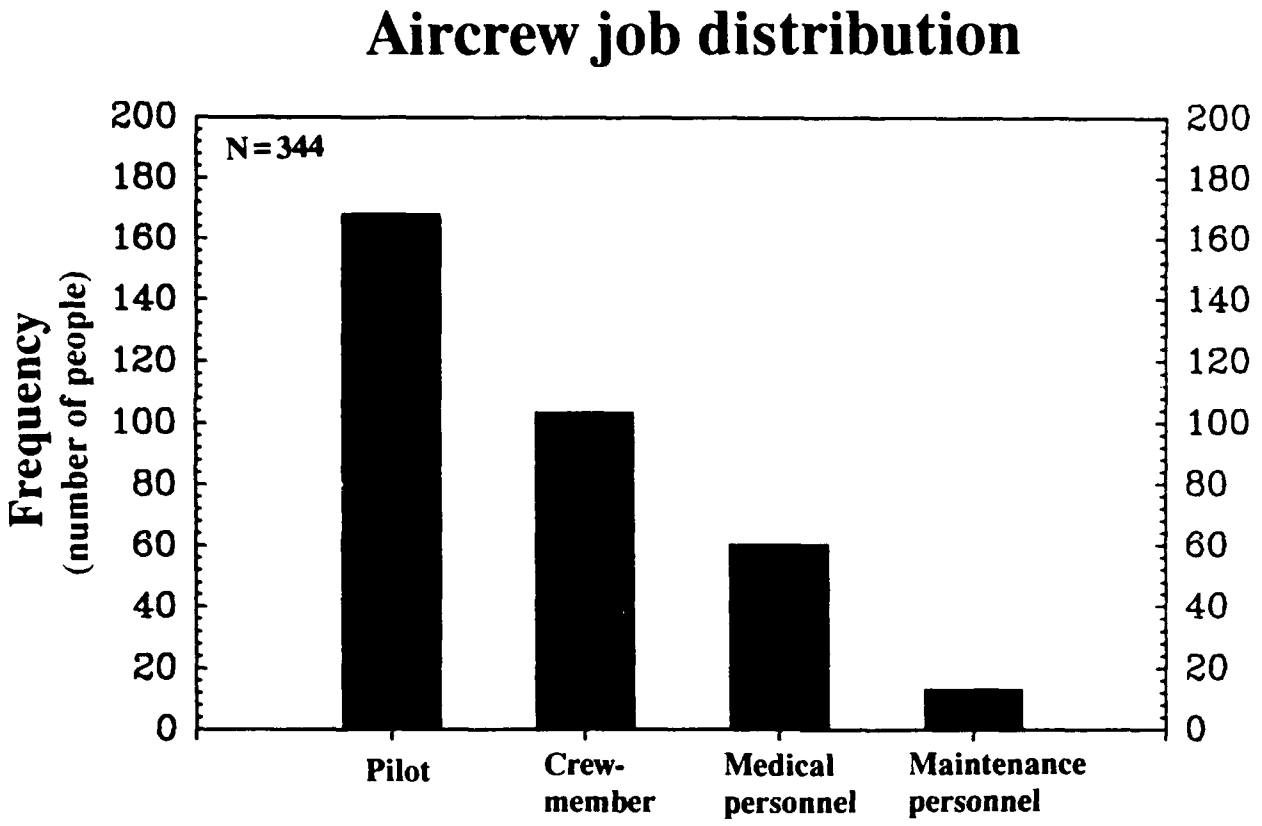


Figure 47. Aircrew job distribution.

The original, Armywide protocol used a three-tier contact lens fitting system, with the initial lens of choice being a moderate to high water content disposable extended wear soft lens. Backup lenses consisted of a low water content standard extended wear soft lens utilized on a disposable basis, and a rigid gas permeable (RGP) lens used with a chemical disinfection system. Both types of soft lenses had analogous diameters and base curves (14.0 mm and 8.8 mm, respectively). The RGP lenses were not utilized on Operation Desert Storm because of concerns for possible foreign body intrusion from blowing dust and dirt. Limited RGP use by Desert Storm participants from the original Army-wide protocol confirmed this concern.

The soft lens wearers were provided with a sterile, unpreserved, unit-dose wetting solution for use as needed. Because of the problems in achieving adequate hygiene in extreme field conditions, an extended wear regimen was selected over daily wear. Since contaminated solutions and cases have been implicated as a possible source of infection, the elimination of the storage, cleaning, and disinfection processes was projected to balance out the increased risk of infection by extended wear.

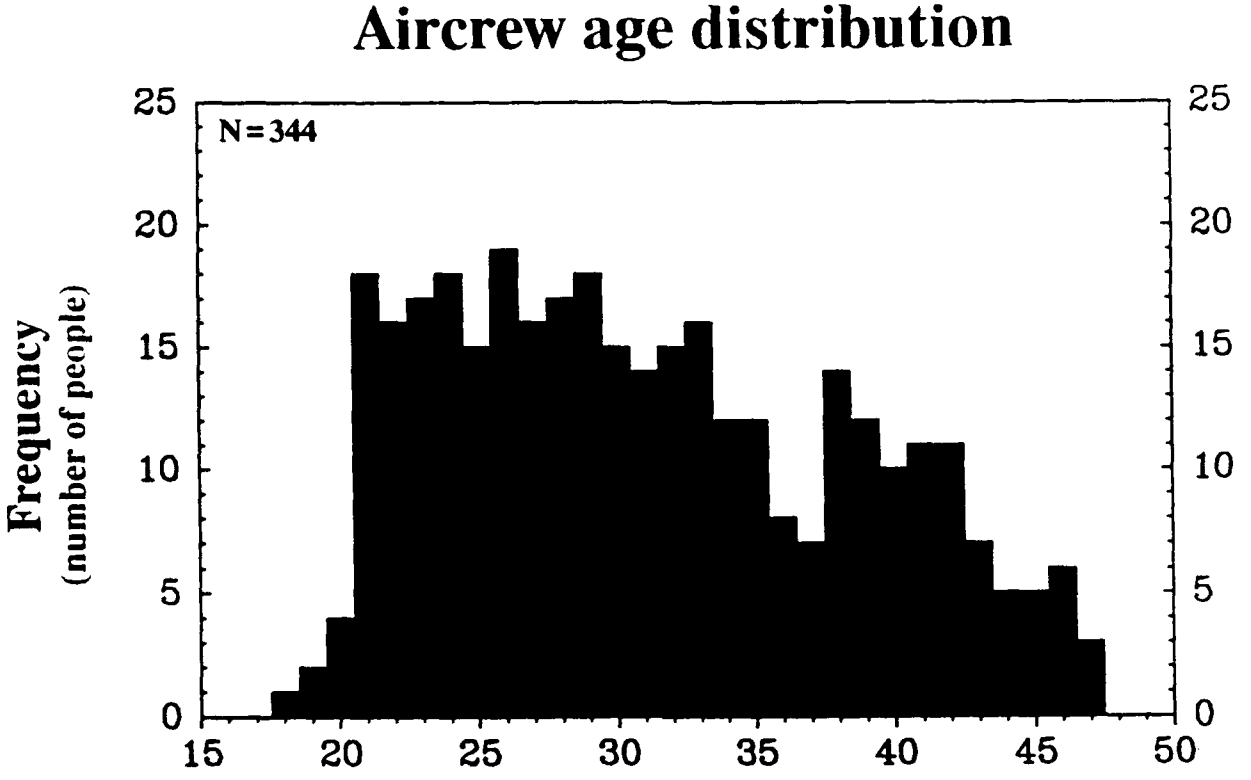


Figure 48. Aircrew age distribution.

Desert Shield/Storm subjects were advised to follow a conservative 3 day/2 night wearing schedule. The subjects were instructed that the night of lens removal was to be passed without any new lens wear; worn soft lenses were to be discarded and new lenses applied in the morning.

Results

There were 501 volunteer subjects; 344 subjects were successfully fitted from the two soft contact lens types used in the original protocol. The 157 unsuccessful attempts fell into 4 general groupings (Figure 50). The refractive error distribution varied from -5.50 D to +2.75 D, peaking at -1.00 D (Figure 51). Subjects ranged in age from 18 to 47. Despite the adverse environmental conditions, quarterly followup exam results did not vary in a clinically significant manner from those at the initial fittings (Figures 52-60). However, some statistically significant differences were noted.

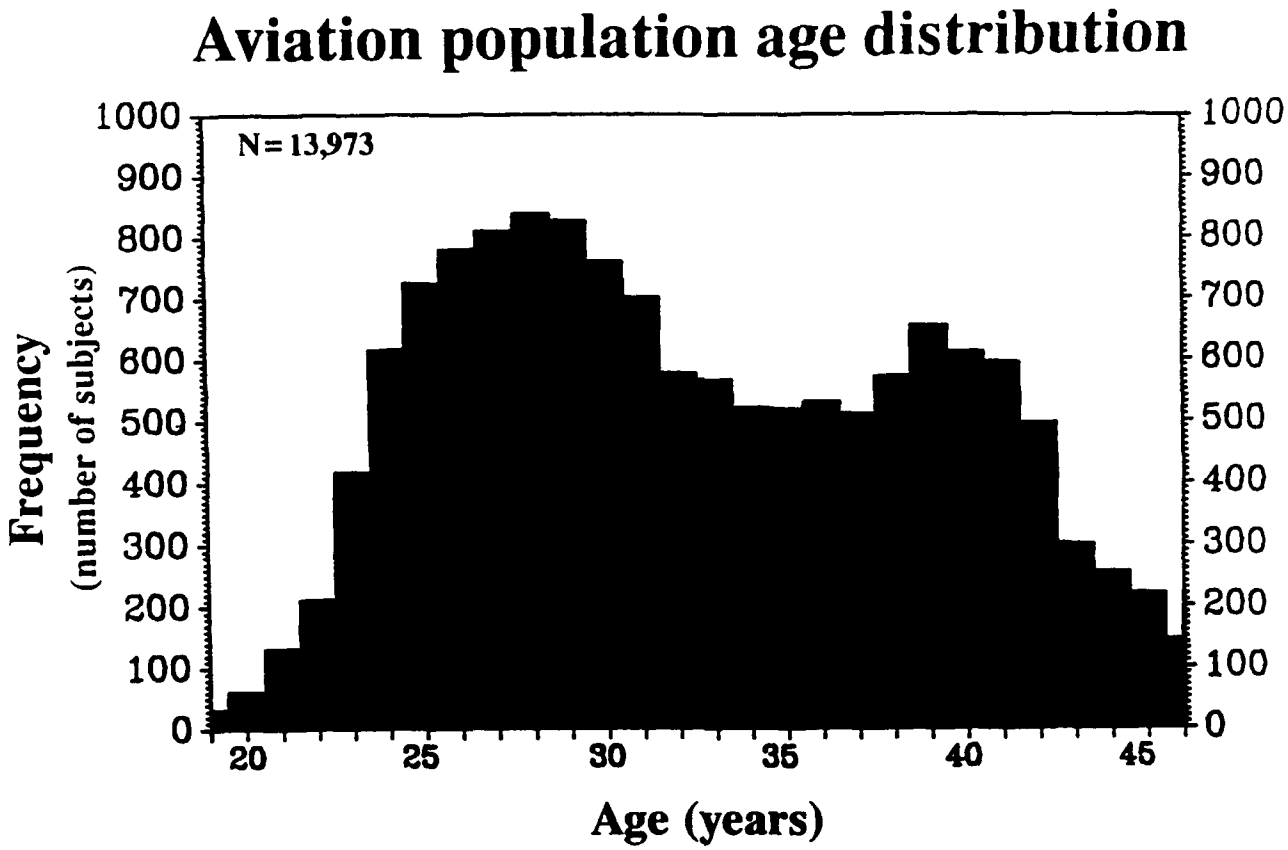


Figure 49. Aircrew population age distribution.

Discussion

By two-sample nonparametric analysis, there were minimal/no changes in appraisal of the tarsal conjunctiva ($p=0.32$), corneal edema assessments ($p=0.27$), tear BUT ($p=0.18$), and tear production ($p=0.13$). Mild to moderate changes were evident in evaluation of the bulbar conjunctiva ($p=0.08$), corneal vascularization ($p<0.01$), limbal injection ($p<0.001$), rose bengal staining ($p<0.001$), and fluorescein staining ($p<0.001$). However, since the vast majority of assessments were at level 2 or less, these are judged not to be clinically significant. Despite the harsh field environment, contact lens wear, by subjective slit lamp evaluation, was much less stressful than foreseen by the investigators. Lens blink movement also was significantly different on followup ($p<0.001$), this was likely due to lens dehydration and secondary tightening of the lens with wear.

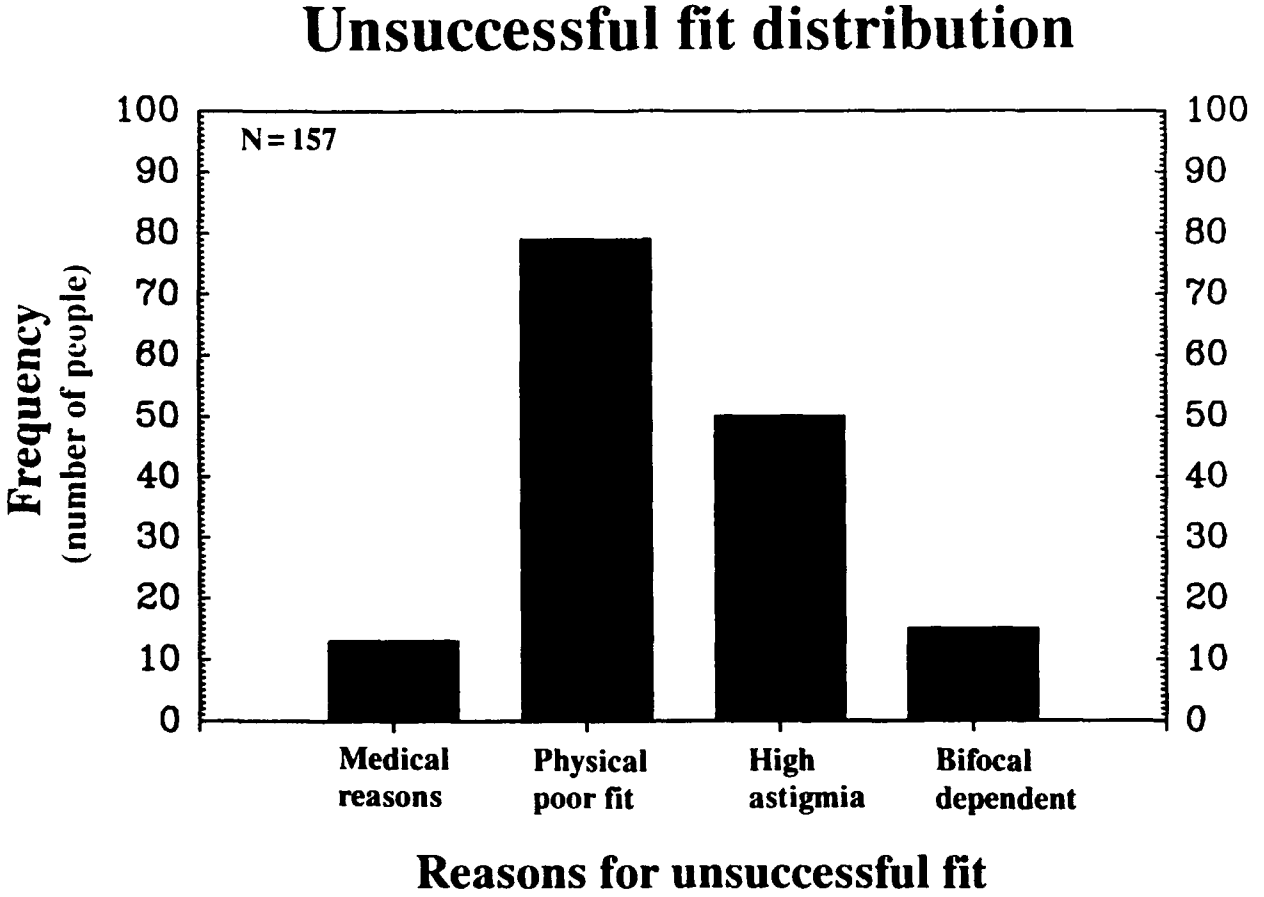


Figure 50. Unsuccessful fit distribution.

Individual assessments of contact lens wear by the subjects was high in garrison, field, and combat conditions, as were subjective performance assessments. Contact lenses were worn in combat by aircrew members serving on seven types Army aircraft. Combat missions included: attack, troop transport, equipment transport, surveillance, intelligence, and medical evacuation. The Apache radar interdiction mission into Iraq on 16 January 1991 consisted of several contact lens wearers, including the mission commander.

One case of ulcerative keratitis occurred during the course of the deployment; there were no ulcers documented during the combat phase of the operation. Three ulcers developed during preparations to redeploy back to home bases, or within 2 weeks after return home. Of these four ulcer patients, one was initially enrolled in the original research protocol, and one was enrolled in the operational protocol. Based on the 344 Desert Shield/Storm subjects, plus the roughly 100+ original AH-64 protocol subjects that served in Southwest Asia, the annualized

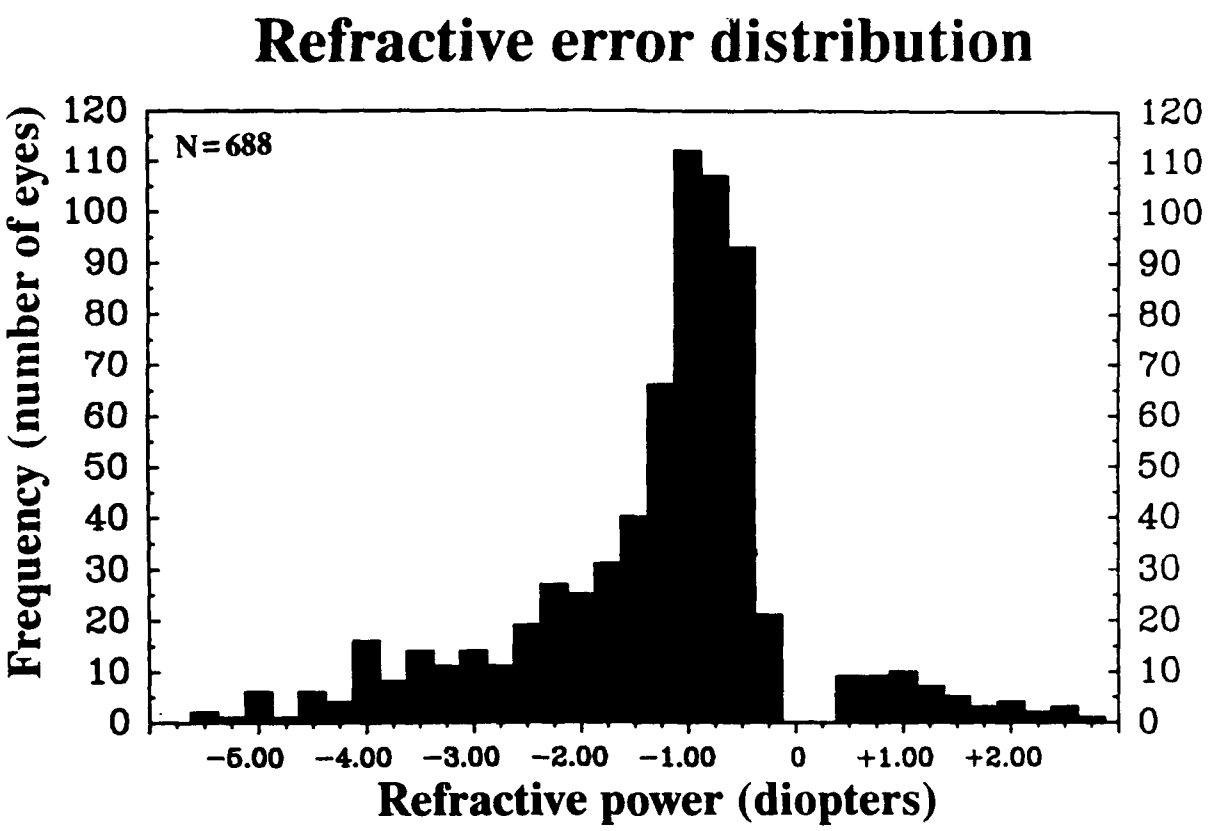


Figure 51. Refractive error distribution.

manifest risk for ulcerative keratitis over the 6-month deployment, was 4/222 lens wearers/year, or 18/1000/year. It should be remembered that three of the four ulcers occurred on redeployment activities; this was perhaps associated with the euphoria over mission success and a lack of attention to lens hygiene issues. Furthermore, the combined risk of all study subjects (all original AH-64 protocol subjects plus Desert Shield/Storm subjects) from November 1988 through September 1991, equated to 1/112/year, or 8.93/1000/year. This combined risk falls well within the wide range of risk estimates (2.1/1000/year to 48/1000/year) proposed for nonaphakic extended soft lens wear in the civilian literature.

Conclusions

Based on the clinical evaluations, subjective feedback, and ocular health risk appraisal data, contact lens wear by Army aircrew is a viable alternative to spectacle wear. However, because of unique difficulties encountered by presbyopes, high astigmats, and those with extreme corneal curvatures (either very flat or very steep), a sizeable portion of spectacle-wearing

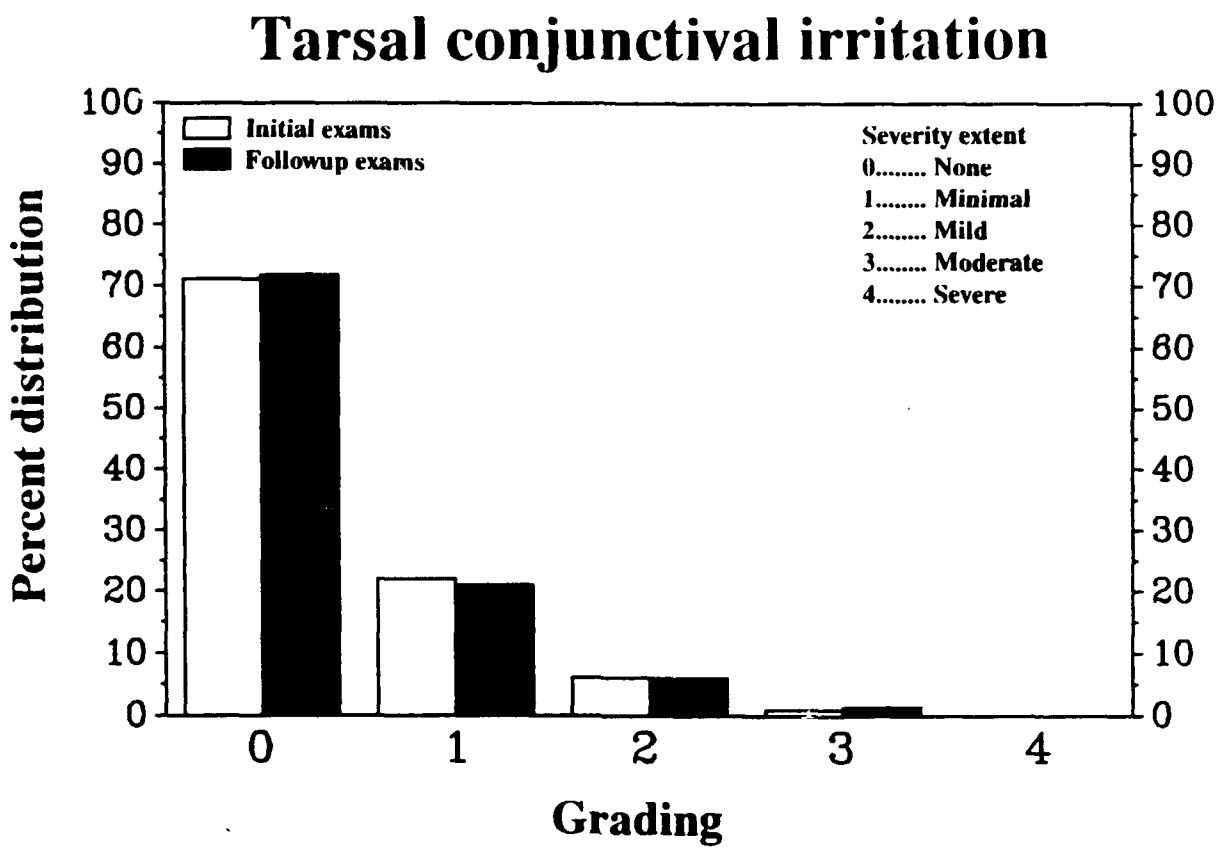


Figure 52. Tarsal conjunctival irritation.

aircrew will not be able to successfully wear contact lenses. Consequently, routine contact lens wear represents only a partial solution to Army aviation's spectacle incompatibility problem. Therefore, developmental hardware alternatives must be included in future system programming or many Army air crewmembers will be prevented from performing certain flight duties.

Assessment of subjective questionnaire data

Introduction

Verbal feedback from the vast majority of aviators was exceedingly positive in nature. However, we were concerned that volunteers were reluctant to report adverse information on a face-to-face basis, so a questionnaire also was used in an attempt to gain information on the program. Specific interest was not limited to performance aspects of lens wear, but also included a rating of the training program and clinical procedures.

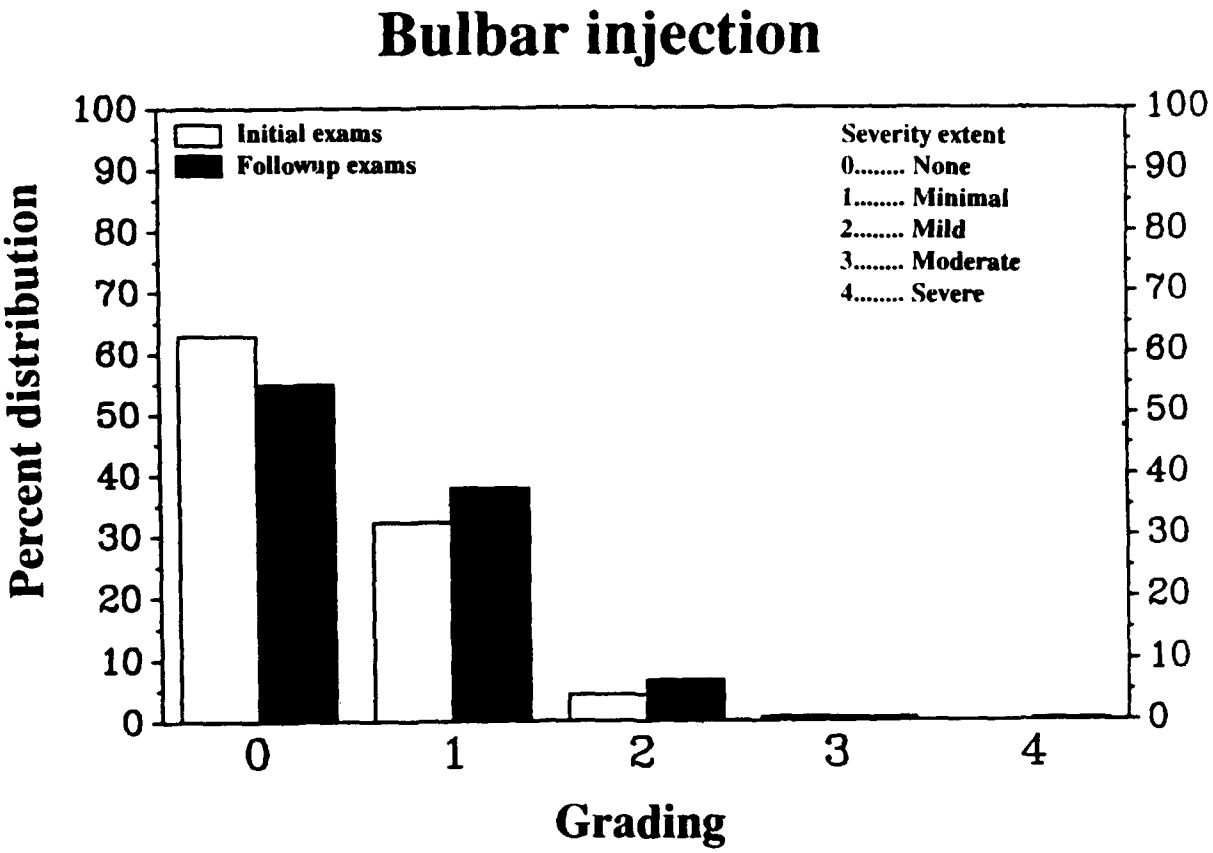


Figure 53. Bulbar injection.

Results and discussion

The questionnaire study participants were located at a combination of nine different U.S. locations and five different European locations. Approximately 40 percent of the original subjects deployed to Southwest Asia for varied durations between 2 August 1990 and 1 May 1991. Almost 90 percent of the subjects wore soft contact lenses and 10 percent wore RGP lenses. The mean age was 33 years, with participants ranging in age from 19 to 46.

The questionnaires were answered by 202 of the 238 original subjects. Most subjects had an opportunity to respond to the questionnaire twice during the course of the study period. Subject responses are recorded as percent of the total number of replies to each question. Not every individual answered every question. The number of respondents for each question is denoted within [brackets] at the right margin. The data analyses did not quantitatively factor in type of contact lens worn. Anecdotal differences are noted in the discussion text.

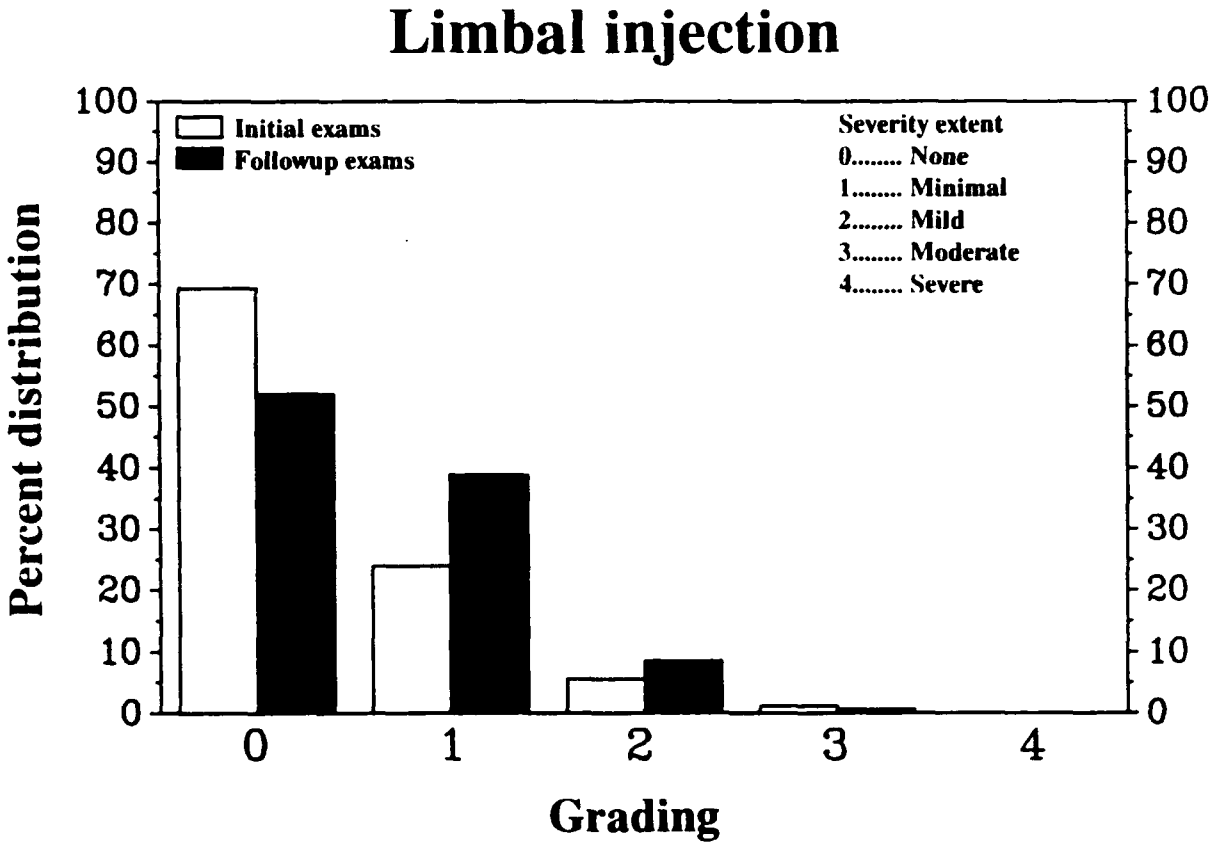


Figure 54. Limbal injection.

Handling of lenses and training

The aircrew members used in this study were assigned to either AH-64 attack units or special operations aviation units. Since women were excluded by regulation from serving in combat duty positions, all study participants except two, were male. The two female aviators were UH-60 pilots assigned to aviation brigade headquarters, but attached to the combat maneuver battalion. The survey made an abbreviated attempt at assessing efficiency of the training procedures, since most people are unlikely to have any degree of confidence at working with or near their eyes. Training occurred in this study on a one-on-one basis, with the trainer demonstrating on his/herself prior to the subject attempting the procedures. Subjects were supervised until they could apply and remove their contact lenses a total of four times prior to release.

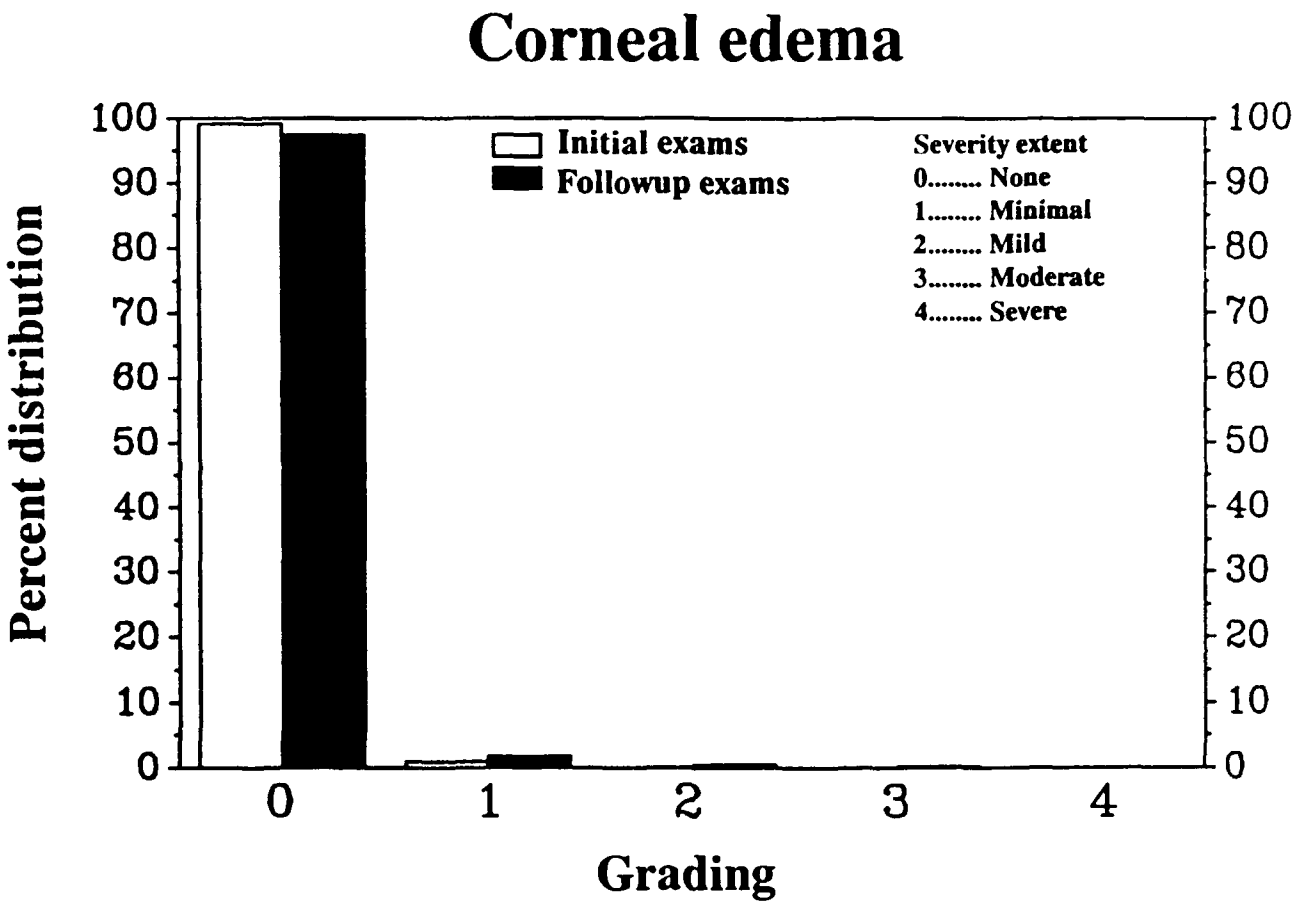


Figure 55. Corneal edema.

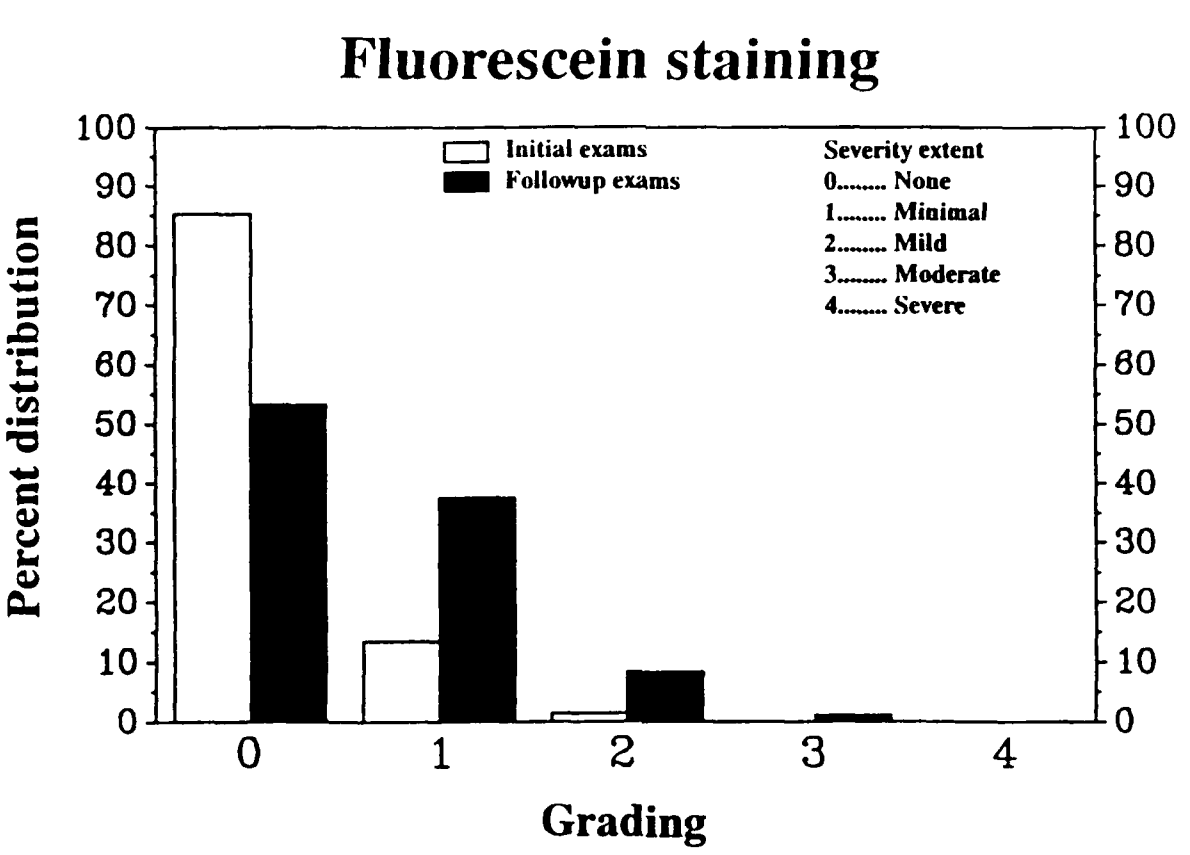


Figure 56. Fluorescein staining.

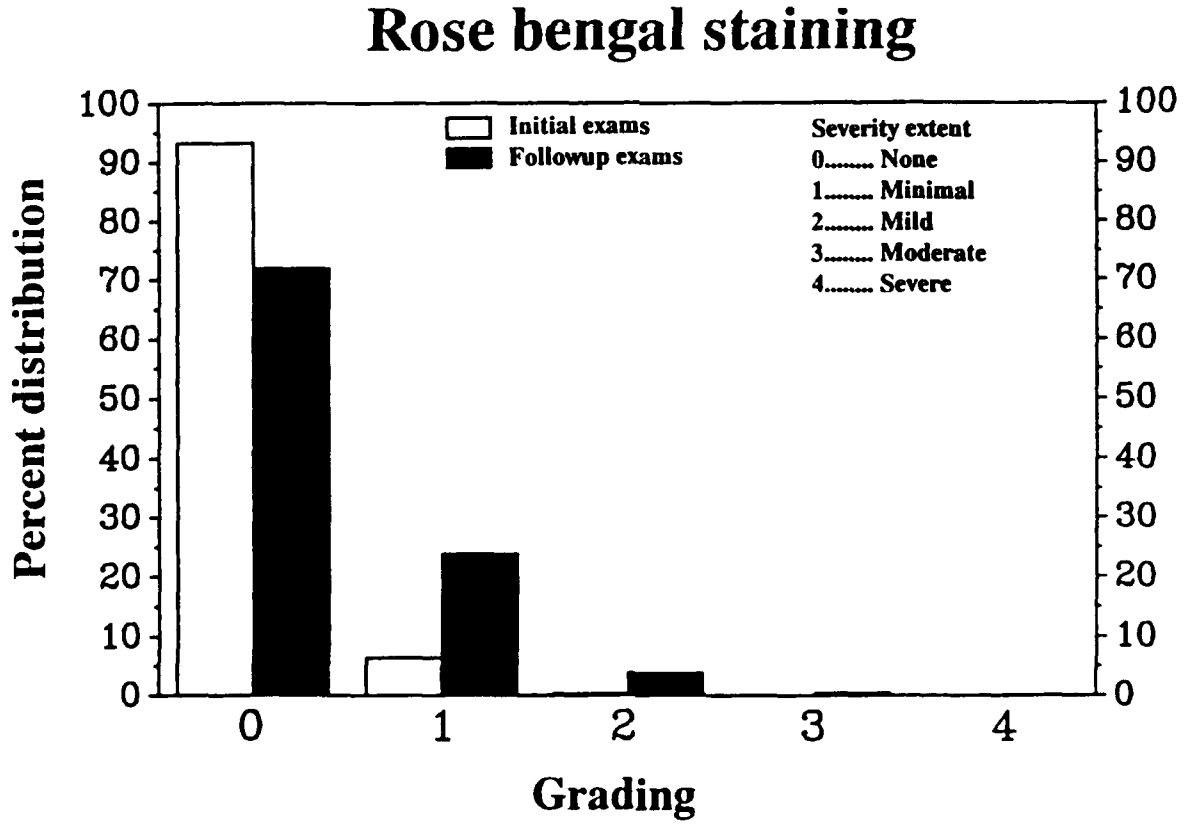


Figure 57. Rose bengal staining.

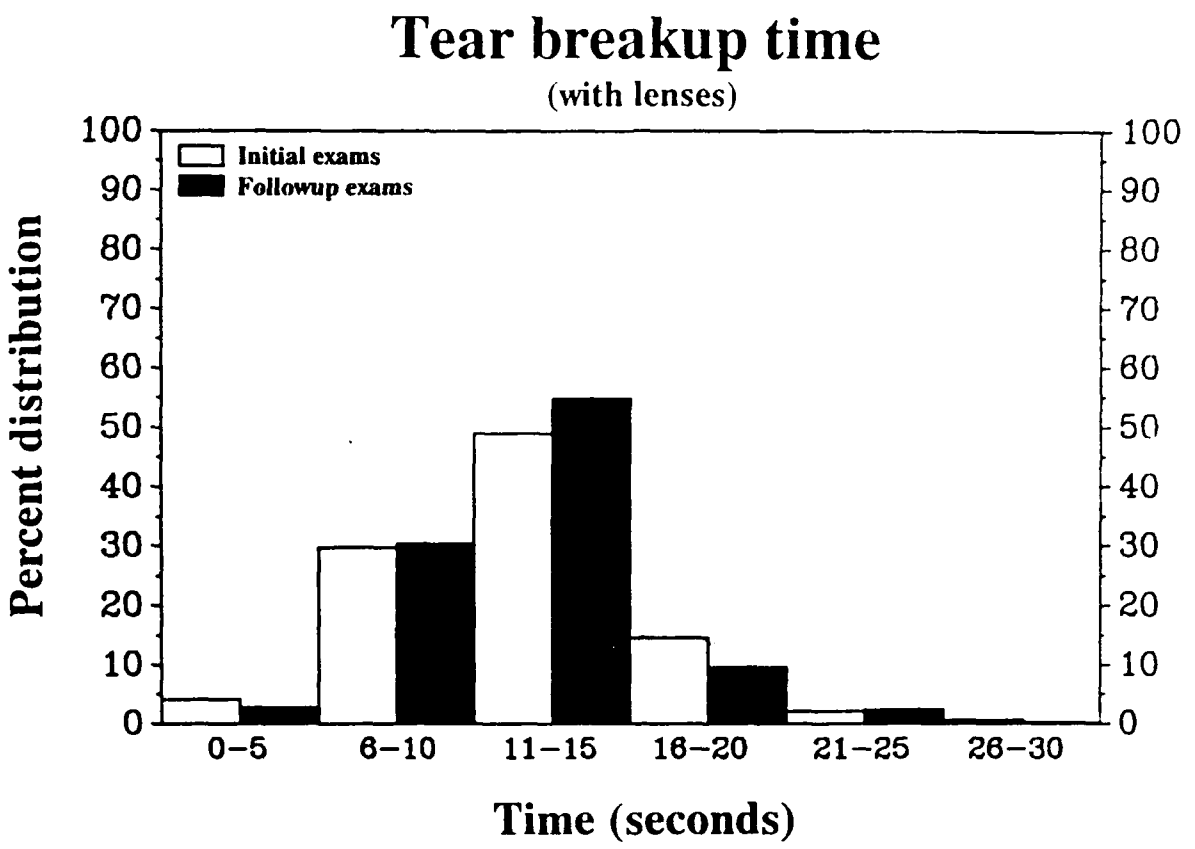


Figure 58. Tear breakup time (with lenses).

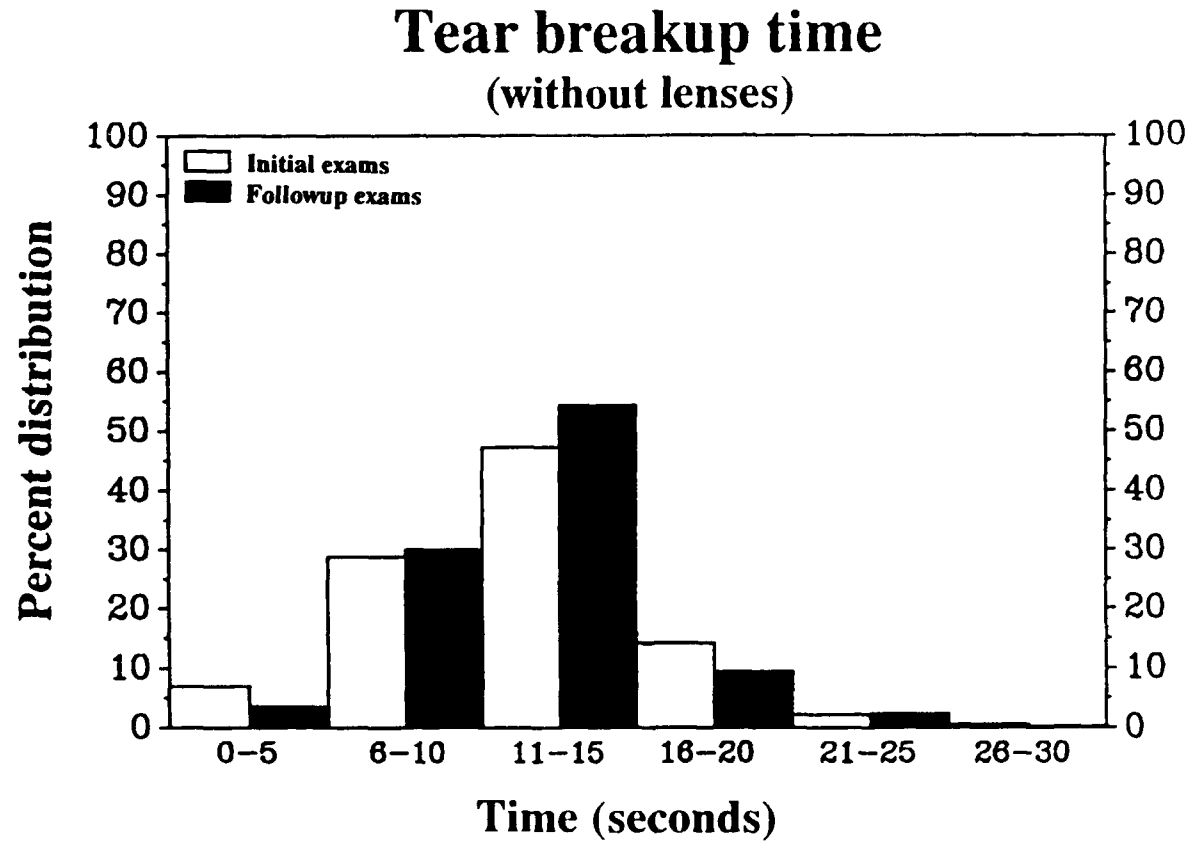


Figure 59. Tear breakup time (without lenses).

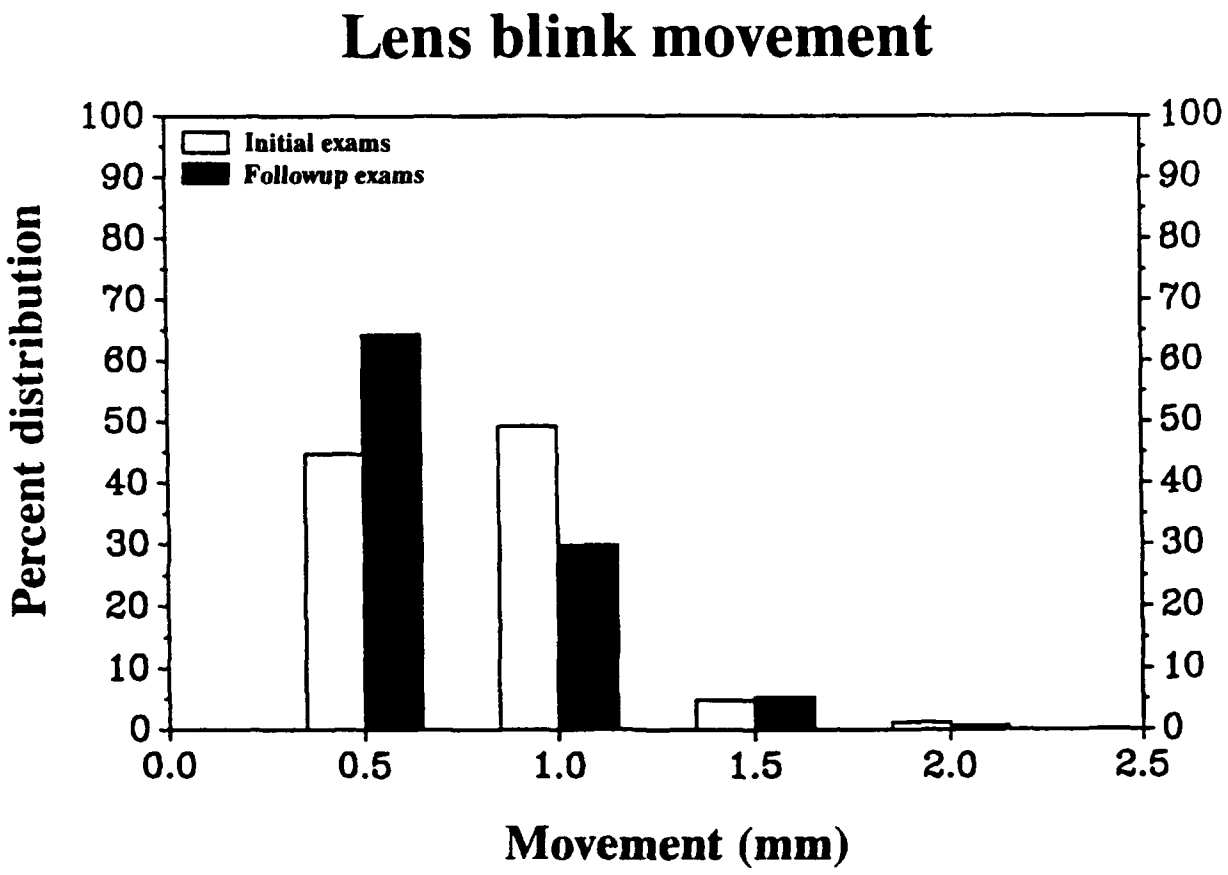


Figure 60. Lens blink movement.

Please rate your experiences in applying your lenses. [359]

40% No problems what-so-ever.
48% Minimal problems
11% Minor problems
1% Moderate problems
<1% Severe problems

Please rate your experiences in removing your lenses. [359]

74% No problems what-so-ever.
22% Minimal problems
3% Minor problems
<1% Moderate problems
<1% Severe problems

Looking back over the course of your contact lens wearing experience, please evaluate the training program effectiveness in teaching you the following aspects: [357]

	Excellent	Good	Fair	Poor	Ineffective
Application	74%	25%	1%	0%	0%
Removal	78%	22%	0%	0%	0%

The above results and their quantitative statistical comparison (chi square=47.323; $p < 0.0001$) suggest that lens removal is an easier procedure to master than lens application. It should be noted that a high chi square value and a very small probability significance level (p) suggest a significant difference between the two response sets. Although 12 percent of respondents felt lens application itself was fairly difficult, only 1 percent felt the shortcoming in lens application was due to any kind of training deficiency. A similar, but smaller pattern exists for lens removal with 5 percent expressing minor to severe problems, while 0 percent implicated any kind of training deficiency causing lens removal difficulties. Indeed, the assessments of application and removal training are not statistically significant (chi square=2.432; p=0.296). It is important to the success of any future clinical program that these established levels of training be met or exceeded.

Comfort/vision

In this section we wished to examine the perceived link between contact lens comfort and subjective quality of vision. In civilian practice, if a clinician is not able to effect a

comfortable contact lens fit, then the final fitting success is compromised no matter how clear the optical or visual result. The following questions were used:

In general, how comfortable are your contact lenses? [356]

52% Very comfortable
40% Comfortable
7% Neither comfortable nor uncomfortable
<1% Uncomfortable
1% Very uncomfortable

How do you rate your vision with contact lenses as opposed to your vision with glasses? [357]

51% Much better with contact lenses
21% Slightly better with contact lenses
17% No difference between contact lenses and glasses
10% Slightly better with glasses
1% Much better with glasses

Responses claiming superior comfort exceeded the superior quality of vision responses. This qualitative comparison of vision between glasses and contact lenses is possibly an indicator of the limited contact lens choice available in the study. A secondary implication is that a comfortable fit is not enough to satisfy the occupational vision needs of Army aircrew. An increase in available lens types and parameters would likely increase the long-term wear success rate.

Environmental conditions

There was some concern that certain weather conditions or problems with glare sensitivity would interfere with flight operations. Weather issues were not necessarily a problem for Apache pilots because their cockpits are enclosed and have heating/air conditioning available. However, the special operations units fly with their aircraft doors off. Therefore, weather conditions would be potentially debilitating for them.

Did any of the following weather conditions make the wearing of contact lenses difficult? [299]

4%	Hot weather	1%	Cold weather
1%	Wet weather	15%	Dry conditions
2%	Sunny weather	20%	Windy weather
50%	Dusty conditions	7%	Other

If there is a problem with light sensitivity, or glare, while wearing the contact lenses outdoors, how dependent are you on sunglasses to alleviate this problem? [349]

- 12% Very dependent, I always wear sunglasses outdoors.
- 28% Moderately dependent, I often wear sunglasses.
- 27% Mildly dependent, I occasionally wear sunglasses.
- 22% Slightly dependent, I rarely wear sunglasses.
- 11% Independent, I never wear sunglasses and have no problem with light sensitivity.

Are you aware of any light sensitivity outdoors while wearing glasses? If so, how dependent are you on sunglasses to alleviate this problem? [349]

- 12% Very dependent, I always wear sunglasses outdoors.
- 30% Moderately dependent, I often wear sunglasses.
- 26% Mildly dependent, I occasionally wear sunglasses.
- 21% Slight dependent, I rarely wear sunglasses.
- 11% Independent, I never wear sunglasses and have no problem with light sensitivity.

Dusty, windy, and dry weather conditions caused the most problems for contact lens wear. Most written comments specifically noted experience in Saudi Arabia as the most oppressive in terms of irritation from the above conditions. Foreign bodies were a problem only for RGP wearers; soft lens wearers complained of initially abnormal lens drying in the desert and a conjunctival stinging or burning sensation secondary to the alkaline pH of the fine dust. Most subjects noticed no difference in irritation from dust with or without contact lenses; some soft lens wearers expressed fewer problems while wearing their lenses, implying some corneal protection. However, RGP lens wearers complained considerably about sand and dust particles producing an uncomfortable foreign body sensation. Preliminary concerns about excessive sensitivity to bright sunlight in the form of glare seem to have been premature. The

subjective comparison between glasses and contact lenses indicates the absence of any statistically significant differential sensitivity to bright sunlight (chi square=0.316; p=0.98). Therefore, based on these responses it can be concluded contact lens wear did not induce sunlight sensitivity problems. This seemed to hold true across all lens types.

Compliance to wearing schedule

Probably the biggest issue of the overall protocol involved possible risk of severe eye infection. Patient noncompliance with directed procedures has been thought to be a major contributor to the incidence of ulcerative keratitis, a potentially sight-threatening condition. The following questions were designed to probe degree of subject compliance.

Since your last exam, how often were you able to stay on the initial 7 day wearing schedule? [347]

37% Always
34% Frequently
13% About half the time
10% Occasionally
6% Never

What was the shortest time you went between lens changes?

15% 6 days
17% 5 days
15% 4 days [347]
23% 3 days
30% 2 days or less

What was the longest time you went between lens changes?

56% 7 days
14% 8 days [344]
5% 9 days
25% 10 days or more

You've been briefed on the hazards of contact lens wear. Are you concerned or worried about those hazards and the possible need for medical treatment, should you develop a problem with contact lens wear.

2% Highly concerned [358]
6% Moderately concerned
16% Mildly concerned
40% Only slightly concerned
36% Not at all concerned

Reported longest and shortest wearing durations were analyzed by the Kolmogorov-Smirnov (KS) method of distribution analysis. A uniform distribution pattern was rejected (p=0.04, indicating the hypothesized distribution is not the correct one) and a normal distribution pattern centered around 7 days continuous wear was accepted (p=0.99). There were both intra- and intersubject variations in typical wearing time duration. While the verbally reported mean wearing time was 4.5 days, approximately 1/4th of the subjects wore their lenses for as little as 2 days at one time or another (mostly RGP lens wearers), and the same fraction admit to having worn a pair of lenses 10 days or longer (soft lens wearers, exclusively). This latter figure is of some concern. Despite repeated cautions at quarterly exams about the dangers of overwear, a significant number of subjects exceeded the recommended limit at some point in the study. This situation is exacerbated by the fact that 75 percent of the subjects really aren't overly concerned about the ocular health risks routine extended contact lens wear can pose. This was a statistically significant deviation from the expected normal distribution around the mildly concerned response (KS; p=0.0016). This public health/preventive medicine issue must be stressed repeatedly in all routine clinical contact lens programs to ensure potentially avoidable infections can be prevented.

General physical lens wear

The general areas of lens comfort and clarity of vision were probed in greater detail with an emphasis on comparing flight activities to garrison activities. The intent of the following questions was to see if operational conditions placed any greater stress visually on the aviator.

Since your last exam, did you experience any of the following problems while flying? Check only those that apply. [358]

	Frequency			
	Never	Rarely	Occasionally	Often
Eye irritation	51%	43%	6%	0%
Eye pain	65%	35%	0%	0%
Blurred vision	52%	47%	<1%	<1%
Dry eye	41%	43%	15%	1%
Light sensitive	60%	32%	7%	1%

If any of the above occurred, how bothersome was it?

	Severity		
	Minor	Moderate	Severe
Eye irritation	91%	9%	0%
Eye pain	98%	2%	0%
Blurred vision	93%	7%	0%
Dry eye	90%	9%	1%
Light sensitive	93%	7%	0%

Since your last exam, did you experience any of the following problems in garrison activities? Check only those that apply.

Frequency [358]

	Never	Rarely	Occasionally	Often
Eye irritation	57%	34%	9%	0%
Eye pain	68%	30%	2%	0%
Blurred vision	53%	40%	7%	<1%
Dry eye	47%	38%	15%	<1%
Light sensitive	58%	34%	8%	<1%

If any of the above occurred, how bothersome was it?

	Severity		
	Minor	Moderate	Severe
Eye irritation	83%	15%	2%
Eye pain	93%	2%	5%
Blurred vision	91%	9%	0%
Dry eye	92%	8%	0%
Light sensitive	91%	9%	0%

Although garrison activities yielded slightly higher ratings of physical discomfort and/or visual complaints than flight activities, there was not a statistically significant difference. Severity comparisons of flight vs. garrison activities were also not significantly different, reinforcing results of the frequency query. Clearly, in-flight activities do not put a greater stress on contact lens wear. A conscious or unconscious bias could have slanted responses away from flight-related complaints. However, one subject, when briefed on the questionnaire results, commented that while flying he is totally unaware of many minor irritations that normally get his attention on the ground. Based on subsequent researcher flight experience, we are inclined to agree with the latter explanation.

Night vision goggles

Since the special operations units had considerable experience flying under night vision goggles, we attempted to assess visual performance with glasses vs. contact lenses. The number of respondents to this question was restricted to aircrew experienced in flight under NVGs.

Please evaluate night vision goggle (NVG) operations while wearing contact lenses. [121]

78%	Much greater readiness and effectiveness with contact lenses
21%	Somewhat greater readiness and effectiveness with contact lenses
1%	No difference between contact lenses and glasses
0	Somewhat greater readiness and effectiveness with glasses
0	Much greater readiness and effectiveness with glasses

Have you noticed any of the following during NVG flight, and under what visual correction conditions? [126]

With spectacles		Observation	With contact lenses	
No	**Yes**		**No**	**Yes**
69%	31%	Halos	92%	8%
47%	53%	Reflections	99%	<1%
54%	46%	Glare	96%	4%
54%	46%	Decreased field of view	100%	0%
100%	0%	Altered color sensitivity	99%	<1%

Since 99 percent of the respondents felt greater readiness and effectiveness on NVG operations while wearing contact lenses, it is probable that NVG flight in contact lenses is less distracting and thereby less hazardous than in spectacles. Only 1 percent felt there was no difference between glasses and contacts, and no one rated glasses over contacts. Furthermore, when specifically questioned about visual distractors, subjects more often noted problems with spectacles. The presence of halos, reflections, glare, and decreased field of view represented significant problems for spectacle wear compared to contact lens wear (chi square=22.72; p=0.00014). Although possible spectacle-incompatibilities within general aviation were not of immediate interest in this study, this comparison highlights the potential benefit of a routine clinical contact lens program for general aviation. Improved NVG flight safety may be a secondary benefit of contact lens use.

M-43 protective mask

The Apache M-43 protective mask was specifically designed for compatibility with the HDU portion of the Apache IHADSS. However, fielding of the mask has not been total, and relatively few Apache pilots have had much in-flight experience with the mask. The following questions were developed for a gross assessment of the mask and the ability to wear contact lenses under the mask.

Have you flown while wearing the M-43 protective mask? [358]
Yes = 32% No = 68%

115 subjects were able to respond to the following questions.

If yes, please assess contact lens comfort under the M-43 mask.

65%	Very comfortable
30%	Comfortable
0%	Neither comfortable nor uncomfortable
5%	Uncomfortable
0%	Very uncomfortable

Please assess comfort of the mask independent of your contact lenses.

23%	Very comfortable
57%	Comfortable
5%	Neither comfortable nor uncomfortable
5%	Uncomfortable
10%	Very uncomfortable

Please assess the quality of your vision under the M-43 mask.

56%	Excellent
17%	Good
22%	Fair
5%	Poor
0%	Unacceptable

Please assess the quality of your vision under the M-43 mask independent of your contact lenses.

15%	Excellent	30%	Good		
30%	Fair	15%	Poor	10%	Unacceptable

While the vast majority of subjects responded in a positive fashion to contact lens comfort and visual performance under the mask, a far lesser proportion rated the mask itself positively. This difference was statistically significant (chi square=49.531; $p<0.00001$). Since the mask could not be flown by these subjects without contact lenses (there are no other refractive error correction alternatives under the mask), there may be a built-in bias toward a negative mask assessment. A comparison of responses from emmetropes would help resolve this disparity. These relatively adverse mask assessments are disconcerting, since the Army has already adopted a version of the M-43 for general aviation.

Safety of flight

A major investigative concern involved adequacy of flight safety assessment. While an earlier portion of the questionnaire looked at possible distractions created by contact lens wear, this section sought to examine activity changes induced by lens wear. Baseline activity in the form of control transfer was initially documented, then contact lens-induced control transfer was assessed. Subjects were asked to perform a safety of flight assessment based on their experiences.

What was the typical flight duration during the past quarter?
2.74 hours (mean)

Approximately how often, during a typical flight prior to your participation in this study, did you have to hand over the controls because of an activity not directly related to the mission (ie, adjust seat, stretch legs, adjust helmet)?
1.2 (mean) [358]

Approximately how often, during a typical flight during this study, did you have to hand over the controls because of an activity not directly related to the mission (ie, tend to contact lenses)? 1.1 (mean) [358]

Have you had to use the rewetting drops during flight? [358]
Yes = 28% No = 72%

If yes, how often during a typical flight? [100]
79% Rarely to never
19% 1-2 times per flight
2% 3-5 times per flight
0 6-8 times per flight
0 >8 times per flight

Have you ever had to hand over the controls in order to tend to your contact lenses? Yes = 13% No = 87% [359]
If so, what activity was required? Add Rewetting Drops

...and how often did this occur within the course of a typical flight? 1.1 (mean)

Have you ever had to remove your contact lenses while in flight?
Yes = 4% No = 96% [114]

How often has this occurred? 1

Please assess the impact these activities had on safety of flight [296]

98%	No impact
2%	Slight impact
<1%	Moderate impact
0%	Severe impact

Have you had to use the rewetting drops during nonflight activities? [358]

Yes = 91% No = 9%

If yes, how often? [326]

37%	Rarely to never
49%	1-2 times a day
13%	3-5 times a day
1%	6-8 times a day
0%	>8 times a day

Based on the response data, contact lens wear did not interfere with flight operations and the transfer of the flight controls any more than any other "housekeeping activity" (i.e., adjust seat, stretch legs, adjust helmet). The application of wetting solution was the primary lens maintenance activity reported, although five subjects reported having to remove a lens in the cockpit at least once during the course of the study. While 28 percent reported using the wetting solution in the cockpit, only 13 percent reported having to transfer the controls to tend to their lenses. These two responses agree, since it can be assumed that during a typical flight any one pilot in a two-pilot aircraft would have the controls roughly half the time. The reported use of wetting solution was more closely associated with garrison activities. This could be accounted for because of the time disparity between a 2.74 hour flight and the balance of the duty day. However, bias and/or attention factors could be influencing this response. The final safety assessment was overwhelmingly positive despite acknowledgment of some required contact lens-related activity in the cockpit.

Final assessments

One last set of questions was used to assess overall approval of contact lenses and their influence on flying ability, readiness, and combat effectiveness. A final question attempted to place the subject in a policy-making position concerning the routine fitting of contact lenses for all aviators in the hopes of minimizing any blatant bias that may exist.

Rate your level of confidence in your flying ability when wearing contact lenses as opposed to when wearing glasses. [347]

64% Much more confident with contact lenses
23% Slightly more confident with contact lenses
12% Equally confident with both
<1% Slightly more confident with glasses
<1% Much more confident with glasses

Estimate what your combat readiness and effectiveness might be when wearing contact lenses as opposed to when wearing glasses.

62% Much greater readiness and effectiveness with contact lenses.
33% Somewhat greater readiness and effectiveness with contact lenses.
5% No difference between contact lenses and glasses
0% Somewhat greater readiness and effectiveness with glasses.
<1% Much greater readiness and effectiveness with glasses.

Based on your experience as a contact lens wearing aviator, what kind of endorsement would you give if you were told that the army was considering the routine fitting of contact lenses for all spectacle-wearing aviators? [358]

95% Strongly support
3% Moderately support
1% Neither support nor oppose
1% Moderately oppose
<1% Strongly oppose

As can be seen from the above responses, there was overwhelmingly positive support for contact lens use. The combat readiness and effectiveness question had been designed to be somewhat rhetorical. However, the advent of Operations Desert Shield/Storm made that question a real-life probe of actual performance. Several contact lens wearers were on the 16 January 1991 radar interdiction mission south of Baghdad, and approximately 100 study subjects flew on combat missions while wearing their contact lenses. Despite the environmental stresses of Southwest Asia and the associated combat, contact lenses emerged as a highly contributory, integral part of fielded combat aviation equipment.

Conclusions

The results of this questionnaire portion of the overall study provide a solid foundation for discussion of Army aircrew contact lens policies. Integrated studies examining clinical physiological, ocular health risk, and ocular response issues

will merge to form the comprehensive database necessary to delineate a final policy determination on contact lens use by Army aircrew. Based on the subjective questionnaire responses presented here, we conclude that contact lens wear is suitable for routine Army aircrew use and widely accepted by study subjects as a mission-essential means of overcoming hardware-spectacle compatibility problems.

Overall conclusions

Review of the pertinent issues follows the specific issue sequence established in the report.

1. The refractive error distribution in the overall study, compared to the refractive error distribution of all rated aviators from the AEDR, reveals no significant difference between the two groups (Lattimore and Schrimsher, 1992; in review). A similar statistical unity was established in this report between AH-64 subjects and Desert Shield/Storm subjects. Therefore, Figure 3 can be used by logistics personnel in the initial stockage of lens powers if a routine contact lens program is initiated. Lack of fitting success was primarily due to excessive astigmatism and presbyopia.

2. The subject age distribution matches the AEDR age distribution. The bimodal characterization suggests periodic fluctuations in the prevalence of spectacle wear among aviators for any 1 year. As a result, prevalence of spectacle wear should show an upswing in the near future, but then fall off in 5 to 7 years.

3. Mean corneal limbal vascular development slowly progresses in a linear fashion as a function of amount of time in the study. At the documented rate, exempting individual extremes, it would not represent a significant clinical problem for the wear of contact lenses through a normal career.

4. Rose bengal and fluorescein staining suggest the practical limits of extended soft contact lens wear to be 2 to 5 days, respectively.

5. Tear BUT assessments, using different types of fluorescein, are in fact documenting different aspects of tear film stability. Therefore, one can not substitute for the other. Both tests should be done on the initial exam, and repeated on followup exams when there are subjective patient complaints expressed.

6. The threat of in-flight sudden incapacitation from contact lenses was shown not to exist. Although lens wearers were involved in mishaps, lenses were judged to have been presen', but

noncontributory to the mishap. The projected safety of flight issue did not develop.

7. There were minimal numbers of minor contact lens related complications. This was perhaps minimized by close followup, and detailed subject instruction on how to best care for their eyes and lenses in order to avoid complications.

8. The ability of a soft lens to drape across the cornea is strictly a reflection of the lenses base curve and diameter. Lens thickness and water content do not significantly affect front lens surface curvature or ability to mask astigmatism. As a result, any routine program should include an array of lens parameters in order to optimize physical lens fit for each patient.

9. Corneal aesthesiometry, although a valuable research tool, is not indicated for clinical use because present contact lens materials do not significantly affect corneal sensation thresholds.

10. Sterile, peripheral corneal infiltrates developed in six subjects. They did not present as acute cases, however. All six were detected on followup exam. This highlights the requirement to stress to prospective patients the need for immediate evaluation at the onset of symptoms if a routine program is instituted. On the other hand, the medical support system should have expert personnel collocated with participating units in order to ensure ready accessibility. Peripheral, extended wear, soft contact lens-related ulcers are likely a localized response to endogenous metabolic by-products that are coalesced or concentrated at the periphery of the lens near the limbus, much as carbon dioxide bubbles coalesce in the same location upon decreased ambient barometric pressure.

11. Bacterial ulcers represent a true threat to the vision of contact lens patients, particularly so in the case of soft, extended wear lenses. While the incidence of ulcerative keratitis was not outside the ranges predicted by the civilian literature, from a clinical perspective any ulcer is an unsatisfactory result. In order to minimize this potentially catastrophic complication, planned replacement, flexible wear paradigms (with a 3-day/2-night maximum wearing time) should be pursued in garrison. Wearing time during field operations should be as brief as allowed by mission requirements.

12. Translens oxygen flux data indicate a relative loss of oxygen flow after 5 days of extended wear. Beyond that time less and less oxygen reaches the cornea. Paradoxically, the low water content, nonionic lenses provided better flux after 1 week of wear than the high water content, ionic lenses. Therefore, a

metabolically maximized lens selection for extended wear beyond 3 to 5 days continuous wear, if such a wearing time were operationally necessary, would be a nonionic, low water content lens that has an absolutely minimum center thickness.

13. The water component pH of a soft lens takes 2 or more days to fully stabilize to that of the precorneal tearfilm, and this process does not vary with lens type or packaged pH. It is possible that the transition period affects lens optics, and that the best possible visual performance may not be obtained until the lenses have been in place for a couple of days. Packaging of the lenses at a pH equivalent to that of human tears would circumvent this process. Any routine lens selection program should investigate solution pH of the various brands of lenses.

14. Water content measurements indicate a process of soft lens habituation to the precorneal tearfilm environment. Both types of soft lenses dehydrated over the first 3 or 4 days of wear; the higher water content lenses dehydrated to a greater relative degree on a normalized scale. This process did not vary by measurement technique or by environmental condition. This dehydration process, as well, might limit optimum visual performance until stabilization is reached.

15. The linear correlation of water content as a function of anterior lens surface pH is very high for both lenses. The lens performance data provided by manufacturers often is based on the packaged condition, not the <u>in situ</u> condition. This can be misleading to a busy clinician, and leads to a recommendation that actual <u>in situ</u> material performance data be made available to practitioners routinely providing contact lens care.

16. Ultrasound pachometry, at the moment, is not appropriate for central corneal thickness assessments when there is a risk of corneal edema. Consistently, ultrasound measurements underestimated corneal thickness compared to optical thickness measurements on corneas that have recently supported soft contact lenses. As a result, ultrasound pachometry is not recommended for contact lens practice.

17. Snellen visual acuity with high contrast letters is not an accurate measure of visual performance. The use of low contrast, preprinted charts under low illuminance conditions is capable of segregating poor visual performers from adept visual performers. Results are not contaminated by astigmatism, or by age in the range from 19 to 46. This technique should be adopted as an additional test for all soldiers requiring use of advanced visionic and electro-optical systems.

18. The anatomic term 'endothelial guttata' likely includes a variety of conditions that are expressed by dark areas within the

endothelial matrix on specular microscopy. A clinical means of identifying each specific condition is therefore required but not currently available. In this case report, the subject was stable in the nonlens wearing eye and exhibited endothelial polymegethism to the same degree as eyes without the presence of guttata.

19. Contact lens wearers in this study did not produce more tears on followup as compared to their initial exams. However, as a group, RGP wearers produced fewer tears than soft lens wearers. Schirmer tear testing with a topical anesthetic has greater clinical usefulness than testing without an anesthetic.

20. Operations Desert Shield and Storm highlighted the operational usefulness of soft contact lens wear; it also revealed foreign body problems associated with RGP lenses. Clinical assessments and subjective evaluations were very positive in light of expectations associated with the severe environmental conditions encountered in Southwest Asia. Contact lens wear by Army aircrew has been combat tested and shown to have a legitimate role in Army aviation.

21. Subjective questionnaire data simply confirm the above conclusions. The lenses were widely accepted by study subjects as mission-essential equipment.

22. The final recommendation is that a routine soft contact lens program be instituted for Army aircrew. Planned replacement (spherical and toric) daily wear paradigms are recommended for garrison use. Those same brands of lenses worn in garrison should be used on a flexible wear, periodic disposable basis in the field, with a limitation on extended wear of 3 days/2 nights. In some instances, daily disposable wear may be indicated, and should be accounted for in the budgetary process. These recommendations are made in order to minimize corneal stress and secondary complications. Dedicated optometrists should be authorized and assigned against Aviation Brigade Tables of Organization and Equipment to ensure immediate clinical support is available in the field environment. Finally, the practicality of bifocal contact lens use needs to be evaluated.

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Appendix A.

Initial examination

Initial contact lens exam

Name_____. Rank_____.

SSN_____. Unit_____.

Date/Time_____. Age _____.

Aircraft: AH-64, UH-60, OH-58.
Job title: pilot, crew, FS.

1. Habitual R_x:
OD_____.

OS_____.

2. Visual acuity: OD_____.
(spectacle R_x)
OS_____.

3. Low contrast/ OD_____.
low illuminance
acuity: OS_____.
(spectacle R_x)

4. Keratometry readings:
OD_____.

OS_____.

Auto-refractor readings

OD_____.

OS_____.

5. Tear osmolarity: OD_____mOsm.

OS_____mOsm.

6. Slit lamp examination:

Observation code	Classification
I. Limbal injection	
A. Severity	
No injection	0
Minimal (within normal limits)	1
Mild	2
Moderate	3
Severe	4
B. Location	
Nasal quadrant only	N
Temporal quadrant only	T
Inferior quadrant only	I
Superior quadrant only	S
Two quadrants	X,X
Three quadrants	X,X,X
Circumlimbal	C
II. Bulbar injection	
A. Severity	
No injection	0
Minimal	1
Mild	2
Moderate	3
Severe	4
B. Location	
Superficial vessels (diffuse)	A
Superficial vessels (localized)	B
Deep vessels (diffuse)	C
Deep vessels (localized)	D
Combined involvement	E
III. Corneal edema	
A. Severity	
No edema	0
Faint or minimal	1
Mild	2

Moderate.....3
Severe.....4

B. Type

Central corneal clouding.....C
Diffuse epithelial.....D
Microcystic.....M
Stromal.....S
Striae.....V

IV. Corneal vascularization

A. Extent (from sclero-corneal junction)

0 to 1 mm onto cornea.....0
1 to 1.5 mm onto cornea.....1
1.5 to 2.0 mm onto cornea.....2
2.0 to 3.0 mm onto cornea.....3
>3.00 mm onto cornea.....4

B. Location

Nasal quadrant only.....N
Temporal quadrantonly.....T
Inferior quadrant only.....I
Superior quadrantonly.....S
Two quadrants.....X,X
Three quadrants.....X,X,X
Circumlimbal.....C

V. Inflammation

A. Degree

No inflammation.....0
Faint to slight.....1
Mild.....2
Moderate.....3
Severe.....4

B. Location

Subepithelial infiltrates.....S
Aqueous flare.....A
Iris turbidity.....I
Pupillary miosis.....P

VI. Tarsal conjunctiva

A. Status

No involvement.....0
Faint to slight irritation.....1
Mild.....2
Moderate.....3
Severe.....4

B. Anomaly

Follicles.....F
Papillae.....P
Simple injection.....S

VII. Rose bengal staining

A. Severity

No staining.....0
Faint or minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Type

Bulbar conjunctiva only.....B
Cornea only.....C
Combined.....Q

VIII. Fluorescein staining

A. Severity

No staining.....0
Faint or minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Type

Abrasion.....A
Foreign body.....F
3:9.....N
Punctate.....P
Ulcer.....U

7. Tear BUT (without lenses): OD_____sec. OS_____sec.

8. Corneal sensitivity: OD_____. OS_____.

APPLY TOPICAL ANESTHETIC: Time _____.

9. Schirmer tear test (w/topical anesthesia) OD_____mm. OS_____mm.

10. Corneal thickness (ultrasound): OD_____mm. OS_____mm.

11. Corneal thickness (optical): OD_____mm. OS_____mm.

12. Endothelial cell size variability:

OD_____.

OS_____.

WAIT 30 MINUTES FROM TIME OF ANESTHETIC INSTILLATION, THEN APPLY CL's

13. pH (with lenses) OD_____. OS_____.

14. O_2 uptake rate OD_____mm/sec. OS_____mm/sec.

15. Tear BUT (with lenses): OD_____sec. OS_____sec.

16. Lens blink movement: OD_____mm. OS_____mm.

17. Contact lens R_x

OD_____.
power base curve diameter

_____
manufacturer

OS_____.
power base curve diameter

18. Number of lenses provided/used_____.

19. Number of boxes of solutions used_____.

20. Visual acuity: OD_____.
(contact lenses)
OS_____.

21. Low contrast/ OD_____.
low illuminance
acuity: OS_____.
(contact lenses)

22. Keratometry readings:
OD_____.
(with contact lenses in place)

OS_____.

Autorefractor: OD_____.
(with contact lenses in place)
OS_____.

Appendix B.

Followup examination

Followup contact lens exam

Name_____. Rank_____.

SSN_____. Unit_____.

Date/time_____. Aircraft: AH-64, UH-60, OH-58.

Job title: pilot, crew, FS.

Follow-up type: 24 hour 7 day 30 day 1st qtr 2nd qtr 3rd qtr 4th qtr 5th qtr 6th qtr 7th qtr 8th qtr 9th qtr 10th qtr

1. Number of days present lens has been worn_____.

2. Visual acuity: OD_____.
   (with contact lenses)
   OS_____.

3. Low contrast/ OD_____.
   low illuminance
   acuity: OS_____.
   (with contact lenses)

4. Contact lens R_x
OD_____.
power base curve diameter

manufacturer _____

OS_____.
power base curve diameter

5. Keratometry readings:
OD_____.
(with contact lenses in place)

OS_____.

OD_____.
Autorefractor Readings:

OS_____.

6. pH (with lenses): OD_____. OS_____.

7. O_2 uptake Rate: (thru cl's) OD_____mm/sec. OS_____mm/sec.

8. Slit lamp examination:

Observation classification code

I. Limbal injection

A. Severity

No injection.....0
Minimal (within normal limits).....1
Mild.....2
Moderate.....3
Severe.....4

B. Location

Nasal quadrant only.....N
Temporal " only.....T
Inferior " only.....I
Superior " only.....S
Two quadrants.....X,X
Three quadrants.....X,X,X
Circumlimbal.....C

II. Bulbar injection

A. Severity

No injection.....0
Minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Location

Superficial vessels (diffuse).....A
Superficial vessels (localized).....B
Deep vessels (diffuse).....C
Deep vessels (localized).....D
Combined involvement.....E

III. Corneal edema

A. Severity

No edema.....0
Faint or minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Type

Central corneal clouding.....C
Diffuse epithelial.....D
Microcystic.....M
Stromal.....S
Striae.....V

IV. Corneal vascularization

A. Extent (from sclero-corneal junction)

0 to 1 mm onto cornea.....0
1 to 1.5 mm onto cornea.....1
1.5 to 2.0 mm onto cornea.....2
2.0 to 3.0 mm onto cornea.....3
>3.00 mm onto cornea.....4

B. Location

Nasal quadrant only.....N
Temporal " only.....T
Inferior " only.....I
Superior " only.....S
Two quadrants.....X,X
Three quadrants.....X,X,X
Circumlimbal.....C

V. Inflammation

A. Degree

No inflammation.....0
Faint to slight.....1
Mild.....2
Moderate.....3
Severe.....4

B. Location

Sub-epithelial infiltrates.....S
Aqueous flare.....A
Iris turbidity.....I
Pupillary miosis.....P

VI. Tarsal conjunctiva

A. Status

No involvement.....0
Faint to slight irritation.....1
Mild.....2
Moderate.....3
Severe.....4

B. Anomaly
Follicles.....F
Papillae.....P
Simple injection.....S

9. Tear osmolarity: OD_____mOsm.
OS_____mOsm.

10. Tear BUT (with lenses): OD_____sec.
OS_____sec.

11. Lens blink movement: OD_____mm.
OS_____mm.

Remove old lenses

VII. Rose bengal staining

A. Severity

No staining.....0
Faint or minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Type

Bulbar conjunctiva only.....B
Cornea only.....C
Combined.....Q

VIII. Fluorescein staining

A. Severity

No staining.....0
Faint or minimal.....1
Mild.....2
Moderate.....3
Severe.....4

B. Type

Abrasion.....A
Foreign body.....F
3:9.....N
Punctate.....P
Ulcer.....U

12. Tear BUT OD_____sec. (without lenses): OS_____sec.

13. Corneal sensitivity: OD_____. OS_____.

ADMINISTER TOPICAL ANESTHETIC: Time _____.

14. Schirmer tear test (w/topical anesthesia) OD_____mm. OS_____mm.

15. Endothelial cell size variability:
OD_____.
OS_____.

16. Corneal thickness (ultrasound): OD_____mm. OS_____mm.

Corneal thickness (optical): OD_____mm. OS_____mm.

17. Contact lens R_x
OD_____.
power base curve diameter

manufacturer _____

OS_____.
power base curve diameter

18. Number of lenses dispensed _____.

19. Number of wetting solution boxes dispensed_____.

20. Keratometry readings:

OD_____.
(without contact lenses)

OS_____.

OD_____.
Autorefractor readings:

OS_____.

21. Exit snellen acuity (thru spectacles) OD_____.

OS_____.

22. Exit low contrast low illuminance acuity (thru spectacles) OD_____.

OS_____.

Appendix C.

List of manufacturers

Allergan Inc.
2525-T DuPont Drive
Irvine, CA 92715

Marco
1316 San Marco Blvd.
Jacksonville, FL 32247

Johnson & Johnson (Acuvue)
501 George
New Brunswick, NJ 08903

Konan Camera Research Institute, Inc.
10-29 Miyanishicho
Nishinomiyashi Hyogo

Richmond Products (Aesthesiometer)
1021 S. Rogers Circle
Suite 6
Boca Raton, FL 33487-2894

Appendix D.

Volunteer agreement affidavit

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____, SSN _____,

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal

representative for _____ to participate in "The Use of

Extended Wear Contact Lenses in the Aviation Environment: An Army Wide Study"

(Research study)

under the direction of MAJ Morris Lattimore, OD., Ph.D.

conducted at U.S. Army Aeromedical Research Laboratory

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

See next page

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

Command Judge Advocate, Telephone (301) 663-2065 or AUTOVON 343-2065

at U.S. Army Medical Research & Development Command, Ft. Detrick, Frederick, MD 21702-5012

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, if the person I represent may be required (military volunteer) or requested (*civilian volunteer*) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

_____

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____, SSN _____ having full

capacity to consent and having attained my _____ birthday, do hereby volunteer for _____

_____ to participate in _____

_____

(Research Study)

_____

under the direction of _____

conducted at _____

(Name of Institution)

(Continue on Reverse)

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (*MINOR CHILD*) (*Cont'd.*)

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

MAJ Morris Lattimore, MAJ Rhonda Cornum, or Dr. Kent Jensen

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

Command Judge Advocate, Telephone (301) 663-2065 or AUTOVON 343-2065

at U.S. Army Medical Research & Development Command, Ft. Detrick, Frederick, MD 21702-5012

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix E, AR 40-38 or AR 70-25.)*

SEE ATTACHED INFORMED BRIEFING DOCUMENTS

FITTING OPTOMETRIST: _____

I do ☐ do not ☐ *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN *(If volunteer is a minor)*
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 88

VOLUNTEER INFORMED CONSENT BRIEFING: "The Use of Extended Wear Contact Lenses in the AH-64 Aviation Environment: An Army-Wide Study"

Principal Investigator: MAJ Morris R. Lattimore, Jr.

INTRODUCTION

Volunteers are being sought for participation in a research study involving the use of extended wear contact lenses. The purpose of the study is to determine if ametropic AH-64 aircrewmembers can safely and effectively utilize contact lenses in lieu of their spectacles during flight operations. Volunteer contributions to this study may well help enhance the Army's combat readiness, and will provide valuable information concerning the viability of a possible system-wide endorsement of contact lens wear. Volunteers will be provided with contact lenses to supplement current spectacles; the study is projected to end in September, 1991. At that time, a final decision on the use of contact lenses by certain aviation groups will have to be made.

POTENTIAL BENEFITS TO PARTICIPANTS

The only direct, tangible benefit to study participants is the opportunity to wear extended wear contact lenses on a no-cost trial basis. The decision whether to volunteer or not is strictly an individual one. There will be no adverse consequences if participation is declined, or if later withdrawal from the study is desired.

QUESTIONNAIRES

Several questionnaires will need to be filled out during this study. These will ask for observations and perceptions of contact lens-wear effectiveness; they will also ask for some background information. Additionally, from time to time the unit flight surgeon will need to be briefed on any observations you may have regarding operational aspects of contact lens wear.

INFORMED CONSENT BRIEFING

EYE EXAMINATIONS

All of the eye care procedures to be used are standard, well-accepted clinical tests which involve shining lights into the eyes, looking through various lenses, photographing the eyes, placing a special piece of paper at the edge of the lower eyelid to absorb some tears, using a micro-capillary tube to sample some tears, and gently touching the front part of the eye with a fine hair. None of the tests will involve any risks, other than possibly some minor discomfort.

Participants in the study will utilize extended wear contact lenses through September of 1991; new lenses will be dispensed every 12 weeks at quarterly followup examinations. During the study period each participant will receive contact lens examinations on days 1, 2, and 7. Thereafter quarterly visits will be required. This means a minimum of 10 visits to an eyecare facility over a two year period, with each visit taking up to 2 hours. You will be responsible for taking proper care of your eyes, following the replacement schedule, and reporting to the appropriate eyecare facility for all scheduled appointments.

CONTACT LENSES TO BE USED

Extended wear lenses have been available for about 6 years in this country. The contact lenses selected for use in this study have been approved by the Food and Drug Administration (FDA) for extended wear, which means they can be worn for several days or more without being removed. Persons wearing such lenses should periodically give their eyes a rest by removing the lenses for an over-night period. As a participant in this study, you will be required to remove your lenses at least once every 7 days, resting your eyes overnight. Those subjects wearing soft lenses will throw away the old lenses when they are removed, and apply a new set of lenses the next morning. Those subjects wearing rigid gas permeable contact lenses will apply the appropriate cleaning and disinfecting regimens when the lenses are removed, and reapply those same lenses the following morning. Thorough training will be provided in the proper handling, application, and removal of lenses. It is very important that the proper exchange schedule be followed, and that any one set of lenses not be worn longer than 7 continuous days without giving the eyes an overnight rest period. Each individual should stay acutely aware of the status of his/her eyes and should be sensitive to the medical warning symptoms which require prompt attention. Those symptoms are:

1. Noticeably blurred vision, other than of short duration.
2. Eye irritation which is not eliminated by either comfort drops, or the application of a new lens.
3. Excessive or unusual redness of the eyes.
4. Apparent infection of the eyes.
5. Eye pain of any duration.
6. Excessive tear flow.
7. Swelling of eyelids or eye tissues.
8. Mucous discharge around the eyes.
9. Extreme light sensitivity of recent onset.

RISKS OF WEARING CONTACT LENSES

The only significant source of risk to participants in this study is the actual wearing of the contact lenses in the performance of military and flight duties. The wearing of extended-wear contact lenses has been associated with the following effects:

1. Minor, temporary risks that are usually not serious and do not last very long.

   a. Mild watering of the eyes.
   b. Mild sensitivity to light.
   c. Temporarily blurred vision.
   d. Slight redness of the eyes.
   e. Faint sensation of dryness of the eyes.
   f. Mild feeling of irritation to the eyes.
   g. Mild eye pain.
   h. Slight swelling of the cornea or eyelids.

2. Serious and possibly permanent risks.

   a. Abnormal growth of blood vessels into the cornea.
   b. Scarring of the cornea.
   c. Subtle changes in the cornea which reduce vision.
   d. Eye infections, possibly leading to surgical replacement of the cornea, or loss of an eye.
   e. Decreased corneal capacity to cope with fluid build-up, which can lead to surgical replacement of the cornea, or loss of the eye.

SAFEGUARDS

This project has been approved by the Surgeon General of the U.S. Army. The study has been planned for maximum safety and will be closely monitored by eyecare professionals. Many procedures have been built in to ensure the safety of study participants. These safeguards include:

INFORMED CONSENT BRIEFING

1. Thorough eye examinations.
2. Contact lenses will not be prescribed if deemed medically unsuitable.
3. Training will be provided in the safe use and care of the lenses.
4. Lenses will be replaced on a periodic basis.
5. Contact lens wear will temporarily be suspended if medically indicated.
6. Participation will be discontinued if medically indicated.
7. Medical facilities will be briefed on the project in case of a medical emergency.

Based on preliminary studies, in-flight risks for a standard flight profile are minimal. However, as a safeguard, subjects will be instructed that they can not fly with another contact lens wearing subject; this will also be documented on the formal waiver, which requires both commander and individual signature. Back-up spectacles must be carried at all times in case of lens-wearing difficulties.

HANDLING DATA

Other than the flight waiver, only information arising from serious medical incidents is to be placed in the individual's medical record. Upon termination or conclusion of the study an appropriate entry will be made in the data record. All research data files will be kept in the strictest confidence in accordance with regulations. Raw data forms and computer files will have limited access and will be used for research purposes only. No individual information will be released without expressed written consent.

At the end of the study (30 September 1991), or at withdrawal from the study, all contact lens wear by the former subject will be totally discontinued, unless otherwise specified by separate documentation.

Research point of contact for this protocol is Major Morris Lattimore, AV 558-6807.

I have received a copy of this volunteer consent package.

_____

SIGNATURE OF VOLUNTEER / DATE SIGNED

_____

DISINTERESTED WITNESS / DATE SIGNED

Appendix E.

Volunteer registry data sheet

VOLUNTEER REGISTRY DATA SHEET

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: 5 USC 301; 10 USC 1071-1090; 44 USC 3101; EO 9397.

2. Principal and Routine Purposes: To document participation in research conducted or sponsored by the U.S. Army Medical Research and Development Command. Personal information will be used for identification and location of participant.

3. Mandatory or Voluntary Disclosure: The furnishing of the SSN is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A-INVESTIGATOR INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

1. Study NR: _____ 2. Protocol Title:

3. Contractor (Laboratory/Institute Conducting Study):

4. Study Period: From: 01/___/___ To: 15/___/___
(DA/MO/YR) *(DA/MO/YR)*

5. Principal/Other Investigator(s) Names(s) 6. Location/Laboratory

(1) _____ _____/_____
(Last) *(First)* *(MI)*

(2) _____ _____/_____

(3) _____ _____/_____

PART B-VOLUNTEER INFORMATION

(To Be Completed By Volunteer)

PLEASE PRINT, USING INK OR BALLPOINT PEN

7. SSN:___/___/_____ 8. Name: _____
(Last) *(First)* *(MI)*

9. Sex: M__F__ 10. Date of Birth: __/__/__ 11. *MOS/Job Series:___ 12. *Rank/Grade:____

13. Permanent Home Address (Home of Record) or Study Location Address:

_____
(Street) *(P.O. Box/Apartment No.)*

_____
(City) *(Country)* *(State)* *(Zip Code)*

( )_____
(Perm Home Phone No)

14. *Local Address (If Different From Permanent Address):

_____
(Street) *(P.O. Box/Apartment No.)*

_____
(City) *(Country)* *(State)* *(Zip Code)*

( )_____
(Local Phone No)

15. *Military Unit: _____ Zip Code: _____

Organization: _____ Post: _____ Duty Phone No. ( ) _____

USAMRDC Form 60-R Revised 1 Apr 88 (Supersedes previous editions)

PART C-ADDITIONAL INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study:

17. Is Study Completed: Y___ N___

Did volunteer finish participation: Y___ N___ If YES, Date finished: ___/___/___ *(DA/MO/YR)*

If NO, Date withdrawn: ___/___/___ *(DA/MO/YR)* Reason withdrawn:

18. Did Any Serious or Unexpected Adverse Incident or Reaction Occur: Y___N___ If YES, Explain:

19.*Volunteer Followup: _____

Purpose: _____

Date: ___/___/___ *(DA/MO/YR)* Was contact made: Y___N___ If No action taken, explain:

20.*Hard Copy Records Retired: Place: _____ File NR: _____

21.*Product Information:

Product: _____

Manufacturer: _____

Lot NR: _____ Expiration Date: _____

NDA NR: _____ IND/IDE NR: _____

*Indicates that item may be left blank if information is unavailable or does not apply.
Entries must be made for all other items.

Appendix F.

Medical identification card

In Support of a Research Project,

_____

RANK NAME

Has Been Fitted With CONTACT LENSES

In case of serious injury or disability call _____

or contact _____

_____

_____ as soon as possible.

USAAVNC(USAARL) Fm 246, 1 Jan 85

Appendix G.

Qualitative data.

Extended Wear Contact Lenses in the AH-64 Environment

Name _____ Date _____

Quarterly Follow-Up..1st..2nd..3rd..4th..5th..6th..7th..8th
(circle one)

The attached questionnaire is designed to obtain your opinions concerning the use of extended wear contact lenses in the aviation environment over the past 3 month period. If you have any specific observations you'd like to offer in support of your input, please feel free to do so in the comments section at the end of the questionnaire.

A. Since your last exam, how often did you have problems applying your contact lenses?

_____ Always (4 or more times per month)
_____ Often (3 times per month)
_____ Sometimes (2 times per month)
_____ Seldom (1 tme per month)
_____ Never

B. Please rate your experiences in applying your lenses.

_____ No problems what-so-ever.
_____ Minimal problems
_____ Minor problems
_____ Moderate problems
_____ Severe problems

C. Since your last exam, how often did you have problems removing your contact lenses?

_____ Always (4 or more times per month)
_____ Often (3 times per month)
_____ Sometimes (2 times per month)
_____ Seldom (1 time per month)
_____ Never

D. Please rate your experiences in removing your lenses.

_____ No problems what-so-ever.
_____ Minimal problems
_____ Minor problems
_____ Moderate problems
_____ Severe problems

Extended Wear Contact Lenses in the AH-64 Environment

E. Looking back over the course of your contact lens wearing experience, please evaluate the training program effectiveness in teaching you the following aspects:

	Excellent	Good	Fair	Poor	Ineffective
Application	_____	_____	_____	_____	_____
Removal	_____	_____	_____	_____	_____
Wearing schedule	_____	_____	_____	_____	_____

F. In general, how comfortable are your contact lenses?

_____ Very comfortable
_____ Comfortable
_____ Neither comfortable nor uncomfortable
_____ Uncomfortable
_____ Very uncomfortable

G. How do you rate your vision with contact lenses as opposed to your vision with glasses.

_____ Much better with contact lenses
_____ Slightly better with contact lenses
_____ No difference between contact lenses and glasses
_____ Slightly better with glasses
_____ Much better with glasses

H. Rate your level of confidence in your flying ability when wearing contact lenses as opposed to when wearing glasses.

_____ Much more confident with contact lenses
_____ Slightly more confident with contact lenses
_____ Equally confident with both
_____ Slightly more confident with glasses
_____ Much more confident with glasses

Extended Wear Contact Lenses in the AH-64 Environment

I. Estimate what your combat readiness and effectiveness might be when wearing contact lenses as opposed to when wearing glasses.

_____ Much greater readiness and effectiveness with contact lenses
_____ Somewhat greater readiness and effectiveness with contact lenses
_____ No difference between contact lenses and glasses
_____ Somewhat greater readiness and effectiveness with glasses
_____ Much greater readiness and effectiveness with glasses

J. Since your last exam, how often were you able to stay on the 7 day wearing schedule?

_____ Always
_____ Frequently
_____ About half the time
_____ Occasionally
_____ Never

K. What was the longest time you went between lens changes?

_____ 7 days
_____ 8 days
_____ 9 days
_____ 10 days
____ More than 10 days

L. What was the shortest time you went between lens changes?

_____ 6 days
_____ 5 days
_____ 4 days
_____ 3 days
_____ 2 days or less

M. Did any of the following weather conditions make the wearing of contact lenses difficult?

_____ Hot weather
_____ Wet weather
_____ Sunny weather
_____ Dusty conditions
_____ Cold weather
_____ Dry conditions
_____ Windy weather
_____ Other

Please explain _____

_____

Extended Wear Contact Lenses in the AH-64 Environment

N. Since your last exam, did you experience any of the following problems while flying, and if so, how bothersome were they to you? Check only those that apply.

	Frequency			Severity		
	Rarely	Occasionally	Often	Minor	Moderate	Severe
Eye irritation	_____	_____	_____	_____	_____	_____
Eye pain	_____	_____	_____	_____	_____	_____
Blurred vision	_____	_____	_____	_____	_____	_____
Dry eye	_____	_____	_____	_____	_____	_____
Light sensitivity	_____	_____	_____	_____	_____	_____

O. Since your last exam, did you experience any of the following problems in garrison activities, and if so, how bothersome were they to you? Check only those that apply.

	Frequency			Severity		
	Rarely	Occasionally	Often	Minor	Moderate	Severe
Eye irritation	_____	_____	_____	_____	_____	_____
Eye pain	_____	_____	_____	_____	_____	_____
Blurred vision	_____	_____	_____	_____	_____	_____
Dry eye	_____	_____	_____	_____	_____	_____
Light sensitivity	_____	_____	_____	_____	_____	_____

P. If there is a problem with light sensitivity, or glare, while wearing the contact lenses outdoors, how dependent are you on sunglasses to alleviate this problem?

_____ Very dependent, I always wear sunglasses outdoors.
_____ Moderately dependent, I often wear sunglasses.
_____ Mildly dependent, I occasionally wear sunglasses.
_____ Slightly dependent, I rarely wear sunglasses.
_____ Independent, I never wear sunglasses and have no problem with light sensitivity.

Q. Are you aware of any light sensitivity outdoors while wearing glasses? If so, how dependent are you on sunglasses to alleviate this problem?

_____ Very dependent, I always wear sunglasses outdoors.
_____ Moderately dependent, I often wear sunglasses.
_____ Mildly dependent, I occasionally wear sunglasses.
_____ Slight dependent, I rarely wear sunglasses.
_____ Independent, I never wear sunglasses and have no problem with light sensitivity.

Extended Wear Contact Lenses in the AH-64 Environment

R. You've been briefed on the hazards of contact lens wear. Are you concerned or worried about those hazards and the possible need for medical treatment, should you develop a problem with contact lens wear.

_____ Highly concerned
_____ Moderately concerned
_____ Mildly concerned
_____ Only slightly concerned
_____ Not at all concerned

S. Based on your experience as a contact lens wearing aviator, what kind of endorsement would you give if you were told that the army was considering the routine fitting of contact lenses for all spectacle-wearing aviators?

_____ Strongly support
_____ Moderately support.
_____ Neither support nor oppose.
_____ Moderately oppose
_____ Strongly oppose

T. Types of aircraft and approximate number of hours flown prior to your participation in this study.

_____

_____

_____

U. Types of aircraft and hours flown with contact lenses this quarter.

_____

V. What was the typical flight duration during the past quarter?

_____hours.

W. Have you had to use the rewetting drops during flight? _____

If yes, how often during a typical flight?
_____ Rarely to never
_____ 1-2 times per flight
_____ 3-5 times per flight
_____ 6-8 times per flight
_____ >8 times per flight

Extended Wear Contact Lenses in the AH-64 Environment

X. Have you had to use the rewetting drops during nonflight activities? _____

If yes, how often?
_____ Rarely to never
_____ 1-2 times a day
_____ 3-5 times a day
_____ 6-8 times a day
_____ >8 times a day

Y. Approximately how often, during a typical flight prior to your participation in this study, did you have to hand over the controls because of an activity not directly related to the mission (ie, adjust seat, stretch legs, adjust glasses, etc)? _____

Z. Approximately how often, during a typical flight in the past quarter, did you have to hand over the controls because of an activity not directly related to the mission (ie, adjust seat, stretch legs, tend to contact lenses, etc)? _____

AA. Have you ever had to hand over the controls in order to tend to your contact lenses? _____

If so, what activity was required? _____

...and how often did this occur within the course of a typical flight?

_____

AB. Please assess the impact this had on safety of flight
_____ No impact

_____ Slight impact

_____ Moderate impact

_____ Severe impact

AC. Have you ever had to remove your contact lenses while in flight?____

If so, how many times has this occurred in the past quarter? _____

AD. Please evaluate night operations in contact lenses.

Extended Wear Contact Lenses in the AH-64 Environment

AD. Please evaluate night operations in contact lenses.

_____ Much greater readiness and effectiveness with contact lenses
_____ Somewhat greater readiness and effectiveness with contact lenses
_____ No difference between contact lenses and glasses
_____ Somewhat greater readiness and effectiveness with glasses
_____ Much greater readiness and effectiveness with glasses

AE. Have you noticed any of the following during night flying, and under what visual correction conditions? (check appropriate spaces)

With spectacles	Observation	Contact Lenses
_____	Halos	_____
_____	Reflections	_____
_____	Glare	_____
_____	Decreased field of view	_____
_____	Altered color sensitivity	_____

AF. Have you flown while wearing the M-43 protective mask?_____

AG. If yes, please assess contact lens comfort under the M-43 mask.

_____ Very comfortable
_____ Comfortable
_____ Neither comfortable nor uncomfortable
_____ Uncomfortable
_____ Very uncomfortable

AH. Please assess comfort of the mask independent of your contact lenses.

_____ Very comfortable
_____ Comfortable
_____ Neither comfortable nor uncomfortable
_____ Uncomfortable
_____ Very uncomfortable

AI. Please assess the quality of your vision under the M-43 mask.

_____ Excellent

Extended Wear Contact Lenses in the AH-64 Environment

AI. Please assess the quality of your vision under the M-43 mask.

_____ Excellent
_____ Good
_____ Fair
_____ Poor
_____ Unacceptable

AJ. Please assess the quality of your vision under the M-43 mask independent of your contact lenses.

_____ Excellent
_____ Good
_____ Fair
_____ Poor
_____ Unacceptable

Additional comments_____

_____

_____

_____

_____

_____

Extended Wear Contact Lenses in the AH-64 Environment

E. Looking back over the course of your contact lens wearing experience, please evaluate the training program effectiveness in teaching you the following aspects:

	Excellent	Good	Fair	Poor	Ineffective
Application	_____	_____	_____	_____	_____
Removal	_____	_____	_____	_____	_____
Wearing schedule	_____	_____	_____	_____	_____

F. In general, how comfortable are your contact lenses?

_____ Very comfortable
_____ Comfortable
_____ Neither comfortable nor uncomfortable
_____ Uncomfortable
_____ Very uncomfortable

G. How do you rate your vision with contact lenses as opposed to your vision with glasses.

_____ Much better with contact lenses
_____ Slightly better with contact lenses
_____ No difference between contact lenses and glasses
_____ Slightly better with glasses
_____ Much better with glasses

H. Rate your level of confidence in your flying ability when wearing contact lenses as opposed to when wearing glasses.

_____ Much more confident with contact lenses
_____ Slightly more confident with contact lenses
_____ Equally confident with both
_____ Slightly more confident with glasses
_____ Much more confident with glasses

Initial distribution

Commander, U.S. Army Natick Research, Development and Evaluation Center
ATTN: STRNC-MIL (Documents Librarian)
Natick, MA 01760-5040

Col. Otto Schramm Filho
c/o Brazilian Army Commission Office-CEBW
4632 Wisconsin Avenue NW
Washington, DC 20016

Commander/Director
U.S. Army Combat Surveillance and Target Acquisition Lab
ATTN: DELCS-D
Fort Monmouth, NJ 07703-5304

Commander
10th Medical Laboratory
ATTN: Audiologist
APO New York 09180

Naval Air Development Center
Technical Information Division
Technical Support Detachment
Warminster, PA 18974

Commanding Officer, Naval Medical Research and Development Command
National Naval Medical Center
Bethesda, MD 20814-5044

Deputy Director, Defense Research and Engineering
ATTN: Military Assistant for Medical and Life Sciences
Washington, DC 20301-3080

Commander, U.S. Army Research Institute of Environmental Medicine
Natick, MA 01760

U.S. Army Avionics Research and Development Activity
ATTN: SAVAA-P-TP
Fort Monmouth, NJ 07703-5401

U.S. Army Communications-Electronics Command
ATTN: AMSEL-RD-ESA-D
Fort Monmouth, NJ 07703

Library
Naval Submarine Medical Research Lab
Box 900, Naval Sub Base
Groton, CT 06349-5900

Commander
Man-Machine Integration System
Code 602
Naval Air Development Center
Warminster, PA 18974

Commander
Naval Air Development Center
ATTN: Code 602-B (Mr. Brindle)
Warminster, PA 18974

Commanding Officer
Armstrong Laboratory
Wright-Patterson
Air Force Base, OH 45433-6573

Director
Army Audiology and Speech Center
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